

EPA Reg. No. 2596-165



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

November 22, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)

RE: HARTZ REF #128, EPA Reg. No. 2596-RAG-163
HARTZ REF #129, EPA Reg. No. 2596-RAU-164
HARTZ REF #130, EPA Reg. No. 2596-RAL-165
HARTZ REF #131, EPA Reg. No. 2596-RAI-168

SUBMISSION OF REVISED DATA MATRICES

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting revised Data Matrices for the above listed products. These revisions incorporate all comments provided in the DER's completed in late July and early August of 2011. Requested changes to MRID's are reflected here.

The Agency will now be able to conclude their reviews and assign the proper label text categorizations for the products. Additionally, MRID numbers have been included for all Product Chemistry citations made on behalf of these 4 registrations

If you have any questions or need any additional information, please feel free to call me at (201) 271-4800, ext. 7202 or <mailto:rosenwasser@hartz.com>.


Sincerely yours,


Robert Rosenwasser
Regulatory Affairs Agent

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

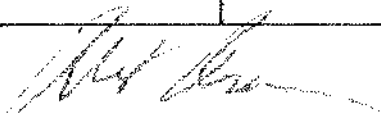
DATA MATRIX

Date November 22, 2011		EPA Reg. No. 2596-RAL		Page 1 of 2	
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #130			
Ingredient Fipronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition	48379002	Hartz	Own	
830-1600	Beginning materials	48379002	Hartz	Own	
830-1650	Description of formulation process	48379002	Hartz	Own	
830-1670	Formation of impurities	48379002	Hartz	Own	
830-1750	Certified limits	48379002	Hartz	Own	
830-1800	Enforcement analytical method	48379003	Hartz	Own	
830-6302	Color	48379001	Hartz	Own	Self-certification
830-6303	Physical state	48379001	Hartz	Own	Self-certification
830-6304	Odor	48379001	Hartz	Own	Self-certification
830-6314	Oxidation/Reduction	Waiver	Hartz	Own	Self-certification
830-6315	Flammability	48379001	Hartz	Own	Self-certification
830-6316	Explosibility	Waiver	End use product is not potentially explosive.		
830-6317	Storage stability	To be submitted	Hartz	Own	In progress
830-6319	Miscibility	Waiver	End use product is not to be diluted with petroleum solvents.		
Signature 			Name and Title Robert Rosenwasser Regulatory Affairs Agent		Date November 22, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date November 22, 2011			EPA Reg. No. 2596-RAL		Page 2 of 2
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #130		
Ingredient Flpronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-6320	Corrosion characteristics	To be submitted	Hartz	Own	In progress
830-6321	Dielectric breakdown voltage	Waiver	End use product is not to be used around electrical equipment.		
830-7000	pH	Waiver	End use product is not to be dispersed with water.		
830-7100	Viscosity	48379001	Hartz	Own	Self-certification
830-7300	Density	48379001	Hartz	Own	Self-certification
870-1100	Acute oral toxicity	43951703	Merial		
870-1200	Acute dermal toxicity	43577706	Merial		
870-1300	Acute inhalation toxicity	Waiver	Merial		
870-2400	Acute eye irritation	44942006	Merial		
870-2500	Acute dermal irritation	44942007	Merial		
870-2600	Skin sensitization	44942008	Merial		
810.3300	Product performance, efficacy	44942105, 44942106, 45612701, 45620501, 45620504, 45620505, 45620506, 445866901, 45866902, 43577715	Merial		
870.7200	Domestic Animal Safety	43863802, 45612702, 45620507, 45143901	Merial		
Signature 			Name and Title Robert Rosenwasser Regulatory Affairs Agent		Date November 22, 2011

PM 10 (1B)

FAST-TRACK AMENDMENTS-Completeness Screening Checklist

Experts In-Processing Signature: Schmidt 5/4/11

EPA Reg. Number: <u>2596-AAL</u>		EPA Receipt Date: <u>5/2/11</u>		
	Check List Item	Yes	No	NA
1	Application Form (EPA Form 8570-1) - signed?	✓		
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?	✓		
3	Certification with Respect to Citation of Data (EPA Form 8570-34) signed?			
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			
5	Data Matrix (EPA Form 8570-35) [Applicable, for adding me-too uses]			
	a) Selective Method?			
	b) Cite-All Method? Applicant owns data or list only the companies offered to pay			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label Included? (5 copies)			
Comments: <u>CSF resubmission for currently pending PAA action (L272)</u> <u>no review needed. No</u> <u>Ivits approved</u>				

Receipt for Section 3

S: 994961

Resubmission: ☐ Yes ☒ No

Regulatory Type: **Product Registration - Section 3**

Fee For Service: ☐ Yes ☒ No

Application Type: **Pending Product Amendment**

Billable: ☐ Yes ☒ No

Company: 2596 THE HARTZ MOUNTAIN CORP

V

Risk Manager: **Registration Division, Risk Management Team 10**

Print Letter

Enter More Information

Tracking

Product #: 2596-RAL Product Name: HARTZ REFERENCE #130

Override#:

Me Too

Me Too

Section 3:

Product Name:

Application Date: 28-Apr-2011



OPP Rec'd Date: 02-May-2011



Front End Date: 02-May-2011



Risk Manager Send Date: 03-May-2011



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

CSF amendment

Receipt Content

Des.

CSF

View/Edit

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

New Ingredient

Request Date:

New Ingredient

Received Date:

Fee for Service

{894961B~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S-

894961

EPA File Symbol/Reg. No.

2596-RAL

Pin-Punch Date:

5/2/2011

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

Inerts approved. I-102 5/5/11

☒ Inert Cleared for Intended Use

☐

Uncleared Inert in Product

Reviewer: *[Signature]*

Date: 5-3-11

Remarks:

Resubmission

waiting on joke

2596-BAL

2/17/11

Memorandum

Date: 02 / 15 / 11

To: PM: 10, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

To the Document Center (ITRMD)

*Please transfer jacket/mini-jacket to the Product Manager Team circled below:

Minor Use Section: **PM -5**

Insecticide Branch: **PM -10** **PM-13**

Herbicide Branch: **PM-23** **PM-25**

Fungicide Branch: **PM-20** **PM-21** **PM-22**


Insect/Rodent Branch: **PM-1** **PM-7**

*Reminder to PM – If applicable, pick-up data from the Screening Room.

Processed by RD's Completeness Check Team



(Team Member Signature)



(Date)



Decision Seq: 445034 Action Code: R310, NEW PRODUCT, NON-FAST TRACK (INCLUDES REVIEWS) ...

Tentative Start Date: 01-Mar-2011 Tentative Ind: Yes FFS Original Decision: ...

Tentative Due Date: 01-Sep-2011 75-Day Due Date: ... FFS EUP Decision: ...

OPP Target Due Dt: ... 21-Day Screen Dt: 01-Mar-2011 FFS Primary Decision: ...

Negotiated Due Dt: ... Start/Stop Clock: ... FQPA Clock: ...

Registrant: [ID] Days Elapsed: ...

Response Due Date: ...

Current Status: PENDING (10-Feb-2011)

Decision Status

Tracking

Create Resubmission

FFS Letters

FFS Letter Decision History

Action Code History

Secondary Decision

☐ Decision Comments
 ☐ Payment
 ☐ Unmatched Payments
 ☐ 75 Day Letters

☐ Meetings & Milestones
 ☐ FFS Information
 ☐ FFS Negotiated Due Dates
 ☐ OPP Target Due Date

☐ Decision Ownership
 ☐ Receipts
 ☐ Data Package
 ☐ Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 889996	Akinlosotu, Ebenezer	2596 RAL	01-Sep-2011	PENDING
NEW REGISTRATION				



III



Receipt for Section 3

S: 889996

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 2596 THE HARTZ MOUNTAIN CORP.

V

Risk Manager: Registration Division: Risk Management Team 10

Product #: 2596-RAL Product Name: HARTZ REFERENCE #130

Override#:

Me Too:

Me Too:

Section 3:

Product Name:

Application Date: 04-Feb-2011



OPP Rec'd Date: 08-Feb-2011



Front End Date: 09-Feb-2011



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content	
Study	
CSF	

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

View/Edit

New registration

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

21-Day Screen Completed by
Contractor

21-Day Expires on 3-1-11

Jacket # 2586 - RAL

MRID# 483790

Content Screen: Recommended to
Pass/Fail

86-5 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Transfer This Jacket to:

Stephen Schnable

Pm 10

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 02-08-2011

Experts In-Processing Signature: JK Kilkinson Date 02-11-11 Fee Paid: Yes

Division management contacted on issues No Yes Date

EPA Reg. Number: <u>2596-RAL</u>		EPA Receipt Date: <u>02-08-2011</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type		X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form) a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)		X		
	yes	no			
	X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)		X		
	Certificate and data matrix consistent		X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)		yes	no	
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)		X		
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)		X		
	a) Selective Method (Fee category experts use)	yes	no		
	b) Cite-All (Fee category experts use)				
	c) Applicant owns all data (Fee category experts use)				
6	5 Copies of Label (link to http://www.epa.gov/oppead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)		X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- A.I. + % Composition are available in OFFIN
- CSF is approved for non-food use
- Data package associated with Submission is consistent with ~~PR~~ notice 86-8.
- * Below are the deficiencies found during Compliance Screening:
- The Extent of use data matrix & Formulators Exemption statement are missing
 - The method of data support selected on form 8570-34 is incorrect
- * Registrant was contacted ^{on} 10:23am, 02/15/2011 to resolve all issues associated with their Submission. Issues have been resolved.
- Jacket approved

NRID: 483790

IK S-4813

* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opphppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Fee for Service

{889996Ã~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 10

Receipt No.

S- 889996

EPA File Symbol/Reg. No.

2596-RAL

Pin-Punch Date:

2/8/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R310

Granted:

R300

Amount Due: \$ ~~1720.00~~ 4807.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: KV Montez

Date: 2/10/11

Remarks:

ISB'S Front-end PRIA Completeness Screen
Draft 3; 10/25/07

EPA Receipt Date: <u>2/8/11</u>		EPA Reg. Number: <u>2596-RAL</u>		
	Check List Item	Yes	No	N/A
1	Has the PRIA Fee been Paid ; is a copy of the check or Pay.gov receipt included in the Submission Package?	✓		
2	Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	✓		
3	Is a Confidential Statement of Formula (EPA Form 8570-29) included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	✓		
4	Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package?		✓	
5	Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package?	✓		
6	Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package?	✓		
7	Is a Label Included in the Submission Package?	✓		
8	Are Data Included in the Submission Package?	✓		
9	Is the Submission an Amendment?			

Explore Registrations

Reg Number: 2596-RAL Reg. Type: Product Registration - Section 3 Status: Under Review (09 Feb 2011)

Name: HARTZ REFERENCE #130

<View Registration Details>

(New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
884961	Pending Product Amendment	02-May-2011	<input type="radio"/> Yes <input checked="" type="radio"/> No	CSF amendment
907708	New Registration	30-Nov-2011	<input checked="" type="radio"/> Yes <input type="radio"/> No	child resistant package testing
910178	New Registration	19-Jan-2012	<input checked="" type="radio"/> Yes <input type="radio"/> No	amended child resistant package testing

...Decisions...

Data Requirements

D: Pending; 445034; 2596-RAL; R310; NEW PRO

75-Day Letters

(ALERT) S: 907614 1/23/2011; New Registr

S: 901778 6/14/2011; New Registration; 259

S: 895488 5/2/2011; New Registration; 259

S: 839896 2/8/2011; New Registration; 259

ALERT S: 911978 Reg #: 2596-RAL

Submission Type: New Registration

Resubmission? ☒ Yes ☐ No

E-Sub #:

Decision #: 445034; R310; NEW PRODUCT; NON-FAST TRACK (INCLUDES

Submitter Company: THE HARTZ MOUNTAIN CORPORATION

Application Date: 18-Jan-2012

OPP Received Date: 19-Jan-2012 Date Sent to Risk manager: 19-Jan-2012

Studies Included? ☐ Yes ☒ No Fast Track? ☐ Yes ☒ No

Form A Signed? ☐ Yes ☐ No ☒ None Date:

Form B Signed? ☐ Yes ☐ No ☒ None Date:

Reviewer: Akinlosotu, Bonaventure

Received DT: Editable Due DT:

Submission Due DT: 08-Mar-2012 Response: 0, 19-Jan-2012

Priority Weight: Priority Points:

Comments: amended CRP package testing

Hartz® Reference # 130

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Dogs

Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® Pro Force™ Dual Action Topical Treatment for Dogs
Hartz® FieldForce™ Dual Action Topical Treatment for Dogs
Hartz® First Defense™ Dual Action Topical Treatment for Dogs

Hartz® Pro Force™ for Dogs
Hartz® FieldForce™ for Dogs
Hartz® First Defense™ for Dogs

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® InControl Max™ Flea (and) (&) Tick Topical Solution for Dogs

Revo Advanced™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® Pro Force™ Dual Action Topical Solution for Dogs
Hartz® FieldForce™ Dual Action Topical Solution for Dogs
Hartz® First Defense™ Dual Action Topical Solution for Dogs

Hartz® Pro Force™ for Dogs
Hartz® FieldForce™ for Dogs
Hartz® First Defense™ for Dogs

FieldForce™ Dual Action Topical Treatment for Dogs
First Defense™ Dual Action Topical Treatment for Dogs
FieldForce™ for Dogs
First Defense™ for Dogs

FieldForce™ Dual Action Topical Solution for Dogs
First Defense™ Dual Action Topical Solution for Dogs

[Each of the above brands will be packaged in the weight classes designated below:]

Weighing Up to 22 lbs.

Weighing 23 to 44 lbs.

Weighing 45 to 88 lbs.

Weighing 89 - 132 lbs.

ACTIVE INGREDIENTS:

Fipronil.....9.80%

(S)-Methoprene.....8.80%

OTHER INGREDIENTS 81.40%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains *(number)* tubes, each ___ fl. oz. (___ ml)

For Dogs and Puppies Weighing:	Net Contents (Each tube)
Up to 22 lbs.	0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.136 fl. oz. (4.02 ml.)

EPA Reg. No. 2596-RAL

EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.

Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panels, and possibly an additional placement on a side panel.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few

days of application, consult a veterinarian immediately. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

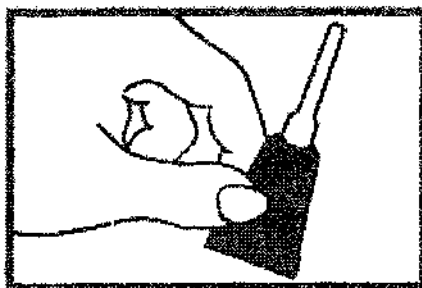
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

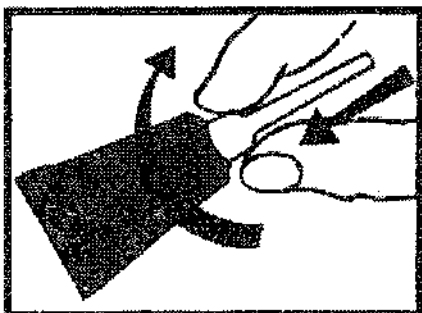
READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER

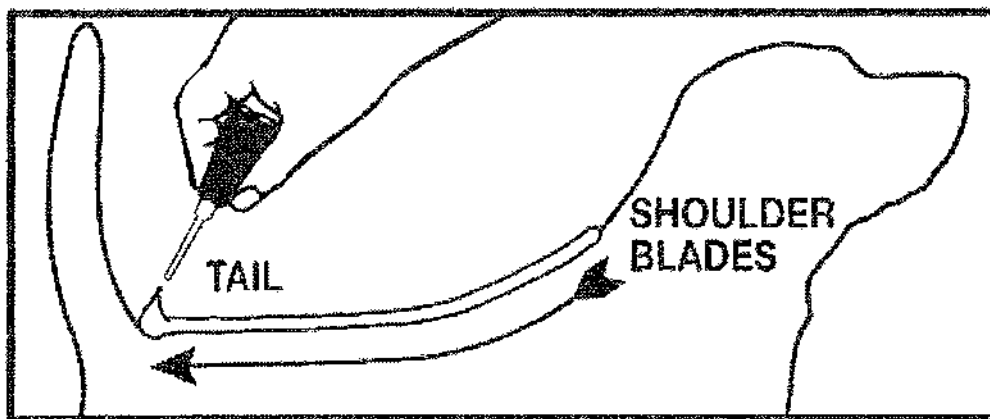
THIS PRODUCT IS APPROVED FOR USE ON ALL DOGS, INCLUDING BREEDING, PREGNANT AND LACTATING BITCHES



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



3 Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

4 Repeat every month.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

[Product name will be followed by weight of dog for which tube is intended]

[A duplicate weight class designation may be printed on the tube]

Active Ingredients:

Fipronil 9.8%, S-Methoprene 8.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

[Range of volumes from 0.023 fl. oz. (.67 ml) to 0.136 fl. oz (4.02 ml) depending upon weight of dog]

EPA Reg. No. 2596-RAL

EPA Est. No.

OPTIONAL/ALTERNATE LABEL TEXT

Weighing up to 22lbs lbs.

Weighing 23 - 44 lbs.

Weighing 45 - 88 lbs.

Weighing 89 -- 132 lbs.

[Adult Fleas]

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on dogs)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for dogs and puppies)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)
(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control)
(Solution)
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)
Gentle protection for dogs (and puppies)
Quick drying (formula)
Dries quickly
Stays on and doesn't rub off
Spreads with dog's natural skin oils
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation
Prevents and controls re-infestation(s)
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Easy spot on topical applicator

Do not reapply product for 30 days

Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Can also be used on breeding, pregnant and lactating bitches
Convenient to use
Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name)
effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles,
and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting
activity against fleas, ticks and chewing lice.

New (Formula) (*claim to be removed after 6 months*)

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).
(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.

Compare to Frontline Plus®

For dogs and puppies 8 weeks of age or older
Specially formulated for dogs and puppies

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

Value pack

(X) month supply

(X) monthly treatment(s)

Fragrance-free

Unscented

Convenient (easy to use) applicator

X Pro-cision Flo® Applicator(s)

(Pro-cision Flo® Applicator)

Direct to your dog's skin

Easy (simple) to use (handle) (apply)

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your dog 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____

Xth Dose _____

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DATA PACKAGE BEAN SHEET

Date: 14-Apr-2011

Page 1 of 1

Decision #: 445034

DP #: (388637)

PRIA

Parent DP #:

Submission #: 889996

*** Registration Information ***

Registration: 2596-RAL - HARTZ REFERENCE #130

Company: 2596 - THE HARTZ MOUNTAIN CORP.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date:

Calculated Due Date: 08-Sep-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 105402, S-Methoprene(8.8%)

129121, Fipronil(9.8%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 14-Apr-2011

Due Back:

DP Ingredient: 105402, S-Methoprene

129121, Fipronil

DP Title: Efficacy

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / IB

Last Possible Science Due Date: 09-Aug-2011

Team Name: Efficacy (IB)

Science Due Date:

Reviewer Name:

C. Myers

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For your review: An R310

Thnx, B.A (703-605-0653)



483790-00

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

February 7, 2011

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Richard Gebken (PM # 10)**
RE: HARTZ REF #128, EPA Reg. No. 2596-RAG
HARTZ REF #129, EPA Reg. No. 2596-RAU
HARTZ REF #130, EPA Reg. No. 2596-RAL
HARTZ REF #131, EPA Reg. No. 2596-RAA

PRIA CODE = R310

Dear Mr. Gebken:

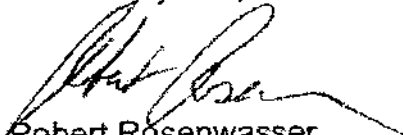
The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing this application to register 4 new products that are based on the Cite-All Method of Support from Merial.

A complete Transmittal Document is attached which states all the documents that are being submitted in support of this registration.

A check for \$19,228 is also enclosed to cover the application fees for the 4 new products and is submitted under PRIA Code R310.

If you have any questions or need any additional information, please feel free to call me at (201) 271-4800, ext. 7202 or <mailto:rosenwasser@hartz.com>.

Sincerely yours,



Robert Rosenwasser
Director, Regulatory Affairs

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094

2. REGULATORY ACTION IN SUPPORT OF WHICH THESE PACKAGES ARE SUBMITTED

Applications for Registration of 4 new products containing:

Fipronil; Hartz Reference #128, EPA File Symbol 2596-RAG

Fipronil; Hartz Reference #129, EPA File Symbol 2596-RAU

Fipronil and (S)-Methoprene; Hartz Reference #130, EPA File Symbol 2596-RAL

Fipronil and (S)-Methoprene; Hartz Reference #131, EPA File Symbol 2596-RAA

3. TRANSMITTAL DATE February 7, 2011

4. LIST OF SUBMITTED DOCUMENTS

For Reference #128, EPA File Symbol 2596-RAG

VOLUME 1	Product Chemistry Self-Certification	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method Method is also applicable to Hartz Reference #129, EPA File Symbol 2596-RAU	(3 copies)

For Reference #129, EPA File Symbol 2596-RAU

VOLUME 1	Product Chemistry Self-Certification,	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method	(See above)

For Reference #130, EPA File Symbol 2596-RAL

48379001 VOLUME 1	Product Chemistry Self-Certification,	(3 copies)
48379002 VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
48379003 VOLUME 3	Product Chemistry: Enforcement Analytical Method Method is also applicable to Hartz Reference #131, EPA File Symbol 2596-RAA	(3 copies)

For Reference #131, EPA File Symbol 2596-RAA

VOLUME 1	Product Chemistry Self-Certification	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method	(See above)

For each application, the following documents are submitted:

1. Completed Application Form (8570-1)
2. Data Matrix
3. Certification with Respect to Citation of Data (8570-34)
4. Data Matrix listing company that is utilized in cite-all method.
5. Completed Confidential Statement of Formulas (One loose copy and one copy in Vol. 2 Product Chemistry)
6. Product labels, 6 copies each.
7. Check in the amount of \$19,228 for 4 applications, PRIA Code R310.

5. COMPANY OFFICIAL Robert Rosenwasser, Director, Regulatory Affairs

6. SIGNATURE

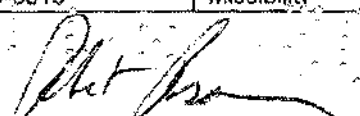
7. PHONE 201-271-4800, ext. 7202

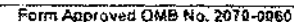


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date February 4, 2011		EPA Reg. No. 2596-RAL		Page 1 of 2	
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #130			
Ingredient Fipronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition	submitted	Hartz	Own	
830-1600	Beginning materials	submitted	Hartz	Own	
830-1650	Description of formulation process	submitted	Hartz	Own	
830-1670	Formation of impurities	submitted	Hartz	Own	
830-1750	Certified limits	submitted	Hartz	Own	
830-1800	Enforcement analytical method	submitted	Hartz	Own	
830-6302	Color	submitted	Hartz	Own	Self-certification
830-6303	Physical state	submitted	Hartz	Own	Self-certification
830-6304	Odor	submitted	Hartz	Own	Self-certification
830-6314	Oxidation/Reduction	Waiver	Hartz	Own	Self-certification
830-6315	Flammability	submitted	Hartz	Own	Self-certification
830-6316	Explosibility	Waiver	End use product is not potentially explosive.		
830-6317	Storage stability	To be submitted	Hartz	Own	In progress
830-6319	Miscibility	Waiver	End use product is not to be diluted with petroleum solvents.		
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date February 4, 2011



Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Date	February 4, 2011	EPA Reg. No. 2596-RAL	Page 2 of 2
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #130	

[illegible]

Date
February 4, 2011



401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date February 4, 2011

EPA Reg. No. 2596-RAL

Page 1 of 1

Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr.,
Secaucus, NJ 07094

Product
Hartz Reference #130

Ingredient Fipronil, (S)-methoprene

[illegible]

Hartz® Reference # 130

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Dogs

Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® Pro Force™ Dual Action Topical Treatment for Dogs
Hartz® FieldForce™ Dual Action Topical Treatment for Dogs
Hartz® First Defense™ Dual Action Topical Treatment for Dogs

Hartz® Pro Force™ for Dogs
Hartz® FieldForce™ for Dogs
Hartz® First Defense™ for Dogs

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® InControl Max™ Flea (and) (&) Tick Topical Solution for Dogs

Revo Advanced™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® Pro Force™ Dual Action Topical Solution for Dogs
Hartz® FieldForce™ Dual Action Topical Solution for Dogs
Hartz® First Defense™ Dual Action Topical Solution for Dogs

Hartz® Pro Force™ for Dogs
Hartz® FieldForce™ for Dogs
Hartz® First Defense™ for Dogs

FieldForce™ Dual Action Topical Treatment for Dogs
First Defense™ Dual Action Topical Treatment for Dogs
FieldForce™ for Dogs
First Defense™ for Dogs

FieldForce™ Dual Action Topical Solution for Dogs
First Defense™ Dual Action Topical Solution for Dogs

[Each of the above brands will be packaged in the weight classes designated below:]

Weighing Up to 22 lbs.
Weighing 23 to 44 lbs.
Weighing 45 to 88 lbs.
Weighing 89 - 132 lbs.

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
OTHER INGREDIENTS	81.40%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains (number) tubes, each __ fl. oz. (__ ml)

For Dogs and Puppies Weighing:	Net Contents (Each tube)
Up to 22 lbs.	0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.136 fl. oz. (4.02 ml.)

EPA Reg. No. 2596-RAL
EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panels, and possibly an additional placement on a side panel.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few

days of application, consult a veterinarian immediately. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER

THIS PRODUCT IS APPROVED FOR USE ON ALL DOGS, INCLUDING BREEDING, PREGNANT AND LACTATING BITCHES

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)

[Option 1 capped tube]

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Pull off cap. Turn the cap around and place on top of tube. Simply press cap down to break the seal of the tube. Remove cap carefully. Position the tip of the tube on the dog's back between the shoulder blades. Use the tip of the tube to part the dog's hair so that the

product will be applied at skin level. (Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the middle of the back.) (Do not bathe your dog 48 hours prior to application.) (Squeeze applicator, applying entire contents in a single spot on the animal's skin) Separate treated dog from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

[Option 2 applicator tube]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip. Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. (Begin squeezing out the contents of the tube to form a stripe as you (move) (glide) from the shoulder blades along the dog's back to the middle of the back.) (Do not bathe your dog 48 hours prior to application.) (Squeeze applicator, applying entire contents in a single spot on the animal's skin) Separate treated dog from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

[Product name will be followed by weight of dog for which tube is intended]

[A duplicate weight class designation may be printed on the tube]

Active Ingredients:

Fipronil 9.8%, S-Methoprene 8.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

[Range of volumes from 0.023 fl. oz. (.67 ml) to 0.136 fl. oz (4.02 ml) depending upon weight of dog]

EPA Reg. No. 2596-RAL

EPA Est. No.

OPTIONAL/ALTERNATE LABEL TEXT

Weighing up to 22lbs lbs.

Weighing 23 - 44 lbs.

Weighing 45 - 88 lbs.

Weighing 89 - 132 lbs.

[Adult Fleas]

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on dogs)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for dogs and puppies)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Gentle protection for dogs (and puppies)

Quick drying (formula)

Dries quickly

Stays on and doesn't rub off

Spreads with dog's natural skin oils

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator
(With) patent pending applicator
Waterproof
Easy spot on topical applicator

Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Can also be used on breeding, pregnant and lactating bitches
Convenient to use
Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name)
effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles,
and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting
activity against fleas, ticks and chewing lice.

New (Formula) (*claim to be removed after 6 months*)

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).
(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered
trademark of Merial.

Compare to Frontline Plus®

For dogs and puppies 8 weeks of age or older
Specially formulated for dogs and puppies

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)
First month, second month, third month (Xth month)
X-pack
X-tubes
Value pack
X month supply
X monthly treatment(s)
Fragrance-free
Unscented
Fresh (scent) (fragrance)
Powder (scent) (fragrance)
Pleasant (scent) (fragrance)
Spring Fresh Scent
Convenient (easy to use) applicator
X Pro-cision Flo® Applicator(s)
X Pro-Glide™ Applicator(s)
(Pro-cision Flo® Applicator) (Now) (featuring the angled)

(Pro-Glide™ Applicator) easily gets through dog's fur, for gentle on-skin application
(Pro-cision Flo® Applicator) (Now) (featuring the angled)
(Pro-Glide™ Applicator) quickly gets through dog's fur, for on-skin application
(Pro-cision Flo® Applicator) (Now) (featuring the angled)
(Pro-Glide™ Applicator) easily penetrates dog's fur, for gentle on-skin application
(Pro-cision Flo® Applicator) (Now) (featuring the angled)
(Pro-Glide™ Applicator) quickly penetrates dog's fur, for on-skin application

New Pro-Glide™ Applicator *(To be used only for the first 6 months)*

Pro-Glide™ Applicator gently glides through the dog's fur
Pro-Glide™ Applicator easily gets through dog's fur to minimize (oily) residue
Pro-Glide™ Applicator easily penetrates dog's fur to minimize (oily) residue
Pro-Glide™ Applicator features rounded edges for gentle on-skin application
Pro-Glide™ Applicator glides smoothly through the dog's fur
Pro-Glide™ Applicator features an angled tip to help guide the application
Easy to use Pro-Glide™ Applicator
Direct to your dog's skin
Easy (simple) to use (handle) (apply)
(Featuring the) (with) EZC™ tube
(Featuring the) (with) EZ2C™ tube
(Featuring the) (with) EZView™ tube
(Featuring the) (with) EZView™ tube
(Featuring the) (with) Clearview™ tube
(Featuring the) (with) Clearview™ tube

(Clearview™) (EZC™) (EZ2C™) (EZView™) tube (visually) ensures all product has been dispensed
(Clearview™) (EZC™) (EZ2C™) (EZView™) tubes give you the assurance all the product has been applied

After application, the treated area may appear wet (or) (oily) for up to 24 hours
You may bathe your dog 48 hours after application
To help remind you when you last applied treatment, simply write in the date when each dose is applied:
First Dose _____
Second Dose _____
Third Dose _____
Xth Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.

Explore Registrations

Reg Number: 2596-RAL Reg. Type: Product Registration - Section 3 Status: Under Review (09-Feb-2011)
 Name: HARTZ REFERENCE #130 <View Registration Details>

(New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
894961	Pending Product Amendment	02-May-2011	<input type="radio"/> Yes <input checked="" type="radio"/> No	CSF amendment

...Decisions...
 Data Requirements
 D: Pending; 445034; 2596-RAL; R310; NEW PRO
 75-Day Letters
 S: 894961 5/2/2011; New Registration; 2596
 S: 894961 2/8/2011; New Registration; 2596

S: 894961 Reg #: 2596-RAL
 Submission Type: New Registration
 Resubmission? ☒ Yes ☐ No
 Decision #: 445034; R310; NEW PRODUCT; NON-FAST TRACK (INCLUDE:
 Submitter Company: THE HARTZ MOUNTAIN CORP.
 Application Date: 28-Apr-2011
 OPP Received Date: 02-May-2011 Date Sent to Risk manager: 09-May-2011
 Studies Included? ☐ Yes ☒ No Fast Track? ☐ Yes ☒ No
 Form A Signed? ☐ Yes ☐ No ☒ None Date:
 Form B Signed? ☐ Yes ☐ No ☒ None Date:
 Reviewer: Akinosatu, Bonaventure
 Received DT: Editable Due DT:
 Submission Due DT: 08-Sep-2011 Response: 02-May-2011
 Priority Weight: Priority Points:
 Comments: Resubmission to existing PRIA

PChem - OK w/Comments (2) (Comments 2, 7 - pg 5)

Tox/PL - Deficient (see Comments 8 & 9 on Pg 3)
 DP 388636

Tox/CAS - Deficient (Comment # 7, pg 3)
 DP 388638

Explore Registrations

Reg Number: 2596-RAL Reg Type: Product Registration- Section 3 Status: Under Review (08-Feb-2011)
 Name: HARTZ REFERENCE #130 <View Registration Details>

(No New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description

- Decisions...
- Data Requirements
- D: Pending; 445034; 2596-RAL; R310; NEW PRO
- 75-Day Letters
- S: 999996 2/8/2011; New Registration; 2596

S: 999996 Reg # 2596-RAL

Submission Type: New Registration

Resubmission? ☐ Yes ☒ No

Decision #: 445034; R310; NEW PRODUCT; NON-FAST TRACK (INCLUDES)

Submitter Company: THE HARTZ MOUNTAIN CORP.

Application Date: 04-Feb-2011

OPP Received Date: 08-Feb-2011 Date Sent to Risk manager: 24-Feb-2011

Studies Included? ☐ Yes ☒ No Fast Track? ☐ Yes ☒ No

Form A Signed? ☐ Yes ☐ No ☒ None Date:

Form B Signed? ☐ Yes ☐ No ☒ None Date:

Reviewer: Akinlosotu, Bonaventure

Received DT: Editable Due DT:

Submission Due DT: 08-Sep-2011 Response: D, 08-Feb-2011

Priority Weight: Priority Points:

Comments: NB/V REGISTRATION

DATA PACKAGE BEAN SHEET

Date: 14-Apr-2011

Page 1 of 1

Decision #: 445034

DP #: (388638)

PRIA

Parent DP #:

Submission #: 889996

*** Registration Information ***

165
Registration: 2596-RAL - HARTZ REFERENCE #130

Company: 2596 - THE HARTZ MOUNTAIN CORP.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date:

Calculated Due Date: 08-Sep-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 105402, S-Methoprene(8.8%)

129121, Fipronil(9.8%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 14-Apr-2011

Due Back:

DP Ingredient: 105402, S-Methoprene

129121, Fipronil

DP Title: CAS

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 09-Aug-2011

Team Name: TOX

Science Due Date:

Reviewer Name: Backus, Byron

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For your review: An R310

Thnx, B.A (703-605-0653)

R310
#28777

8-31

DATA PACKAGE BEAN SHEET

Date: 14-Apr-2011

Page 1 of 1

Decision #: 445034

DP #: (388636)

PRIA

Parent DP #:

Submission #: 889996

*** Registration Information ***

Registration: 2596-RAL - HARTZ REFERENCE #130

Company: 2596 - THE HARTZ MOUNTAIN CORP.

Risk Manager: RM 10 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Bonaventure Akinlosotu BAKINLOS

Sent Date: Calculated Due Date: 08-Sep-2011

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT:NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIS

Ingredients: 105402, S-Methoprene(8.8%)

129121, Fipronil(9.8%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 14-Apr-2011

Due Back:

DP Ingredient: 105402, S-Methoprene

129121, Fipronil

DP Title: Tox/PL

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 09-Aug-2011

Team Name: TOX

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

For your review: An R310

Thnx, B.A (703-605-0653)

R310
#128723

8-31

Explore Registrations

Reg. Number: 2595-RAL Reg. Type: Product Registration Section 9 Status: Under Review (09-Feb-2011)
 Name: HARTZ REFERENCE #130 <View Registration Details>

(New Receipts)

S	Submission Type	OPP Rec'd Date	Resubmission	Description
884981	Pending Product Amendment	02-May-2011	<input type="radio"/> Yes <input checked="" type="radio"/> No	CSF amendment

- Decisions...
- Data Requirements
- D: Pending: 445034, 2596-RAL, R310, NEW PRO
- 75-Day Letters
- S: 901778 6/14/2011; New Registration; 259
- S: 885498 7/2/2011; New Registration; 259
- S: 889996 2/8/2011; New Registration; 259

S: 885468 Reg # 2595-RAL

Submission Type: New Registration

Resubmission? ☒ Yes ☐ No E-Sub #

Decision # 445034; R310, NEW PRODUCT, NON-FAST TRACK (INCLUDES

Submitter Company: THE HARTZ MOUNTAIN CORPORATION

Application Date: 28-Apr-2011

OPP Received Date: 02-May-2011 Date Sent to Risk manager: 09-May-2011

Studies Included? ☐ Yes ☒ No Fast Track? ☐ Yes ☒ No

Form A Signed? ☐ Yes ☐ No ☒ None Date:

Form B Signed? ☐ Yes ☐ No ☒ None Date:

Reviewer: Akinfosolu, Bonaventure

Received DT: Editable Due DT:

Submission Due DT: 08-Mar-2012 Response: 0 02-May-2011

Priority Weight: Priority Points:

Comments: Resubmission to existing PRIA

Decision Information for 2596-RAL



Decision Seq: 445034 Action Code: R310, NEW PRODUCT, NON-FAST TRACK (INCLUDES REVIEWS O ...

FFS Start Date: 08-Mar-2011 Tentative Ind: No FFS Original Decision: ...

Due Date: 08-Sep-2011 75-Day Due Date: ... FFS EUP Decision: ...

OPP Target Due Dt: ... 21-Day Screen Dt: 08-Mar-2011 FFS Primary Decision: ...

Negotiated Due Dt: ... Start/Stop Clock: FQPA Clock: ...

Registrant: ... Days Elapsed: ...

Response Due Date: ...

Current Status: PENDING (10-Feb-2011)

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

Decision Comments Payment Unmatched Payments 75 Day Letters

Meetings & Milestones FFS Information FFS Negotiated Due Dates OPP Target Due Date

Decision Ownership Receipts Data Package Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S:901778	Akinlosotu, Bonaventure	2596-RAL	08-Sep-2011	PENDING
Addendum to Existing Protocol for CRP				
S:895488	Akinlosotu, Bonaventure	2596-RAL	08-Sep-2011	PENDING
Resubmission to existing PRIA				
S:889996	Akinlosotu, Bonaventure	2596-RAL	08-Sep-2011	PENDING
NEW REGISTRATION				

Viewing Record 1 of 1



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

June 13, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)

**Addendum to Existing Protocol for Child Resistant Packaging
for Products containing Fipronil**

***Hartz Reference #128, EPA File Symbol 2596-RAG
Hartz Reference #129, EPA File Symbol 2596-RAU
Hartz Reference #130, EPA File Symbol 2596-RAL
Hartz Reference #131, EPA File Symbol 2596-RAA***

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting an addendum to our existing protocol to add an additional product tube with laminate construction for testing of packaging to determine whether packages of end-use products containing the active ingredient, Fipronil, are child resistant.

The additional product tube with laminate construction has been included in the protocol for child resistant packaging in the Package Description Section 2.2.2.

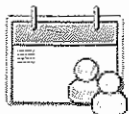
The Hartz Mountain Corporation is submitting the following:

- Hartz Test #2278, Hartz UltraGuard Flea and Tick Topical Treatment, Child-resistant Package Test Protocol, Prepared by National Child Resistant Testing, Inc., Lincoln, NE – 3 copies **dated June 7, 2011.**

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7202 or <mailto:rosenwasser@hartz.com>.

Sincerely,

Robert Rosenwasser
Director, Regulatory Affairs



Conf Call w/RRosenwasser (Hartz's products: 2596-RAA, RAI, RAU, RAG)

Calendar Entry

Wed 11/30/2011 9:00 AM - 10:00 AM

Location: RD Small Conference Room C - S-7671/Potomac Yard One@EPA Rooms: RD Small Conference Room C - S-7671/Potomac Yard One@EPA

Required: Breahn Hanson/DC/USEPA/US@EPA, Richard Gebken/DC/USEPA/US@EPA, Rosalind Gross/DC/USEPA/US@EPA
FYI: Marion Johnson/DC/USEPA/US@EPA

Description

Bonaventure,

Thank you for the quick response. To make things easy for all of us to call in I suggest that we use a toll free conference number.

The number
Passcode:

Rejected; Call in # & code provided to registrant & Breahn to call-in.

I look forward to speaking with you and the rest of the group tomorrow.

Best Regards,


Sean

Sean McNear
Director Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, New Jersey 07094
TEL: 201-271-4800 x 7302
FAX: 201-271-0357

N/A! Per re-negotiation agreement, "all deficiencies must be satisfactorily addressed by 01/8/2012 in order for Agency to meet ^{new} PRA date of 3/8/2012"

→ CRP data sent (via FedEx) to the Agency yesterday, ^{Nov} 29th (copy sent to RO3)

→ Registrant may have to renegotiate (agree) for additional 30 days.

TO 

Re: Conference call
 RRosenwasser
 to:

Bonaventure Akinlosotu
 11/19/2011 07:45 PM

Cc:
 Richard Gebken, Marion Johnson
 Hide Details
 From: RRosenwasser@hartz.com

To: Bonaventure Akinlosotu/DC/USEPA/US@EPA

Cc: Richard Gebken/DC/USEPA/US@EPA, Marion Johnson/DC/USEPA/US@EPA

Bonaventure:

The purpose of the call is to review the status of Hartz applications for fipronil generics, 2596-RAA, RAI, RAU, and RAG. Hartz wants to review the finalization of the CRP data (the final report is being written), its submission to EPA and the current timeline for review and approval of the data relative to the already extended PRIA date. I think that yourself and Richard would be sufficient. If you feel that Rosalind Gross should be on the call, then invite her if she is available.

Let me know if you need more information.

Robert

215.715.6419

Akinlosotu.Bonaventure@epamail.epa.gov

11/18/2011 04:12 PM

To: RRosenwasser@hartz.com

Cc: Gebken.Richard@epamail.epa.gov, Johnson.Marlon@epamail.epa.gov

Subject: Re: Conference call

Specifically, what are we discussing? In order to know who should be invited from my end, I need more information.

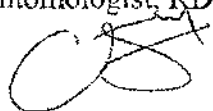
Thanks,

B.A

Efficacy Review

Date: April 5, 2011

Efficacy Reviewer: Clayton Myers, Ph.D., Entomologist, RD-IB
myers.clayton@epa.gov
703-347-8874



45-12

Risk Manager Rev.: Bonaventure Akinlosotu

Products: Hartz Reference #131

EPA Reg. #: 2596-RAA

A.I.'s: Fipronil (9.8%), S-Methoprene (11.8%)

Decision #s: 445037

DP #s: 388643

Submission: R310 (New Product, includes RD Science Review)

MRIDs: CITE-ALL, offer to pay to Merial

GLP: No

Entomologist's Observations/Discussion:

The cited database was deemed acceptable by the Agency, to support a number of efficacy claims on the pioneer product (EPA Reg. No. 65331-4), a combination spot-on product for cats. The proposed claims for the proposed product are nearly identical to that product, with the exception of a proposed 3 month control claim for fleas.

All claims for 3 month control of fleas must be deleted or revised to 6 weeks, as listed below with ~~strike through~~ text. All other proposed efficacy claims are acceptable.

Claims to be deleted/modified (page 5):


-“Kills (Adult) Fleas (~~for up to 3 months~~)”

-“Kills fleas that may cause (flea allergy dermatitis)(and)(flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (~~3 months~~) (on cats)”

Efficacy Review

Date: April 5, 2011

Efficacy Reviewer: Clayton Myers, Ph.D., Entomologist, RD-IB
myers.clayton@epa.gov
703-347-8874



4-5-12

Risk Manager Rev.: Bonaventure Akinlosotu

Products: Hartz Reference #128

EPA Reg. #: 2596-RAG

A.I.'s: Fipronil (9.7%)

Decision #s: 445036

DP #s: 388607

Submission: R310 (New Product, includes RD Science Review)

MRIDs: CITE-ALL, offer to pay to Merial

GLP: No

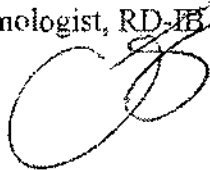
Entomologist's Observations/Discussion:

The cited database was deemed acceptable by the Agency, to support a number of efficacy claims on the pioneer product (EPA Reg. No. 65331-3), a spot-on product for dogs. The proposed claims for the proposed product are nearly identical to that product. All proposed efficacy claims are acceptable.

Efficacy Review

Date: April 5, 2011

Efficacy Reviewer: Clayton Myers, Ph.D., Entomologist, RD-FB
myers.clayton@epa.gov
703-347-8874



4-5-12

Risk Manager Rev.: Bonaventure Akinlosotu

Products: Hartz Reference #130

EPA Reg. #: 2596-RAL

A.I.'s: Fipronil (9.8%), S-Methoprene (8.8%)

Decision #s: 445034

DP #s: 388637

Submission: R310 (New Product, includes RD Science Review)

MRIDs: CITE-ALL, offer to pay to Merial

GLP: No

Entomologist's Observations/Discussion:

The cited database was deemed acceptable by the Agency, to support a number of efficacy claims on the pioneer product (EPA Reg. No. 65331-5), a combination spot-on product for dogs. The proposed claims for the proposed product are nearly identical to that product. All proposed efficacy claims are acceptable.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of Chemical Safety and Pollution
Prevention

Office of Pesticide Programs
Registration Division (7505P)

CHILD RESISTANT PACKAGING REVIEW

March 29, 2012

MEMORANDUM

Subject: Name of Pesticide Products: Hartz Reference #128, #129, #130, #131
Product Type: Insecticide (flea and tick product)
EPA File Symbols: 2596-RAG, -RAU, -RAL and -RAA
DP Barcodes: 399060, 399061, 399062, 399063
Decision Nos.: 445036, 445035, 445034, 445037
MRIDs: 486846-01 through -06
Action Code: R310
PC Codes: 129121 Fipronil
105402 (S)-Methoprene

From: Breann Hanson, Biologist *B Hanson*
Technical Review Branch (TRB)
Registration Division (RD; 7505P)

Through: Rosalind Gross, Ph.D. *Rosalind Gross*
TRB
RD; 7505P

To: Bonaventure Akinlosotu, RM Team 10
Insecticide Branch
RD; 7505P

Applicant: The Hartz Mountain Corporation

FORMULATIONS FROM LABEL:

Hartz Reference #128, 2596-RAG (Dogs)

<u>Active Ingredient:</u>	<u>% by wt</u>
129121 Fipronil	9.70

Hartz Reference #129, 2596-RAU (Cats)

<u>Active Ingredient:</u>	<u>% by wt</u>
129121 Fipronil	9.70

Hartz Reference #130, 2596-RAL (Dogs)

<u>Active Ingredients:</u>	<u>% by wt</u>
129121 Fipronil	9.80
105402 (S)-Methoprene	8.80

Hartz Reference #131, 2596-RAA (Cats)

Active Ingredients:		% by wt
129121	Fipronil	9.80
105402	(S)-Methoprene	11.80

ACTION REQUESTED: The Risk Manager requests that TRB review the 6 submitted Child Resistant Package (CRP) studies for EPA File Symbols: 2596-RAG, -RAU, -RAL and -RAA.

SUMMARY: Based on the current assessment (data reviewed herein), all Senior Adult Use Effectiveness (SAUE) and Child Resistant Effectiveness (CRE) CRP testing data requirements have been met for the 3-tube package presentations for the 0.67 mL fill volume, the 1.34 mL fill volume, the 2.68 mL fill volume and the 4.02 mL fill volume for EPA File Symbols: 2596-RAG and -RAL, as well as the 0.5 mL fill volume for EPA File Symbols: 2596-RAU and -RAA. The CRP certifications for EPA File Symbols 2596-RAG, -RAL, -RAU, and -RAA (all dated 29/NOV/2011) are acceptable. The labels submitted (email to B. Hanson and R. Gross, label revision date 27/MAR/2012) have the same instructions used in the SAUE testing (see "Packaging" section, below).

BACKGROUND: The Hartz Mountain Corporation (herein the "registrant") has applied to register 4 proposed products; a) Hartz Reference #128, EPA File Symbol: 2596-RAG, a fipronil containing product for use on dogs, b) Hartz Reference #129, EPA File Symbol: 2596-RAU, a fipronil containing product for use on cats, c) Hartz Reference #130, EPA File Symbol: 2596-RAL, a fipronil and s-methoprene containing product for use on dogs, and d) Hartz Reference #131, EPA File Symbol: 2596-RAA, a fipronil and s-methoprene containing product for use on cats. All proposed products are labeled for control of fleas and ticks in dogs or cats.

Protocols were previously submitted and reviewed by TRB (TRB memorandums; B. Hanson, DP Barcode: D388670, 2/JUN/2011, and B. Hanson, DP Barcode: D390544, 14/JUN/2011). The protocols were deemed acceptable provided some minor TRB recommendations were incorporated. Please see previous protocol reviews for details on TRB recommendations.

There are five package presentations; the small tube size (2 mL) contains either a 0.50 mL, 0.67 mL or 1.34 mL fill volume, while the large tube size (7.8 mL) contains either a 2.68 mL or 4.02 mL fill volume. The tubes are constructed of Huntsman P5M6K-048 polypropylene, frosted white and have 0.0185" wall thickness. The caps are constructed of Kepital F30-03 Acetal. The cap is twisted down on the tube tip to puncture an opening. The cap is not removed.

During testing, the tubes were filled with placebo (water); in the final manufactured product, the placebo will be replaced with the fipronil or fipronil and (s)-methoprene containing formulations.

PACKAGING: The packages tested consisted of a series of five different volumes of water filled tubes fitted with an applicator tip. The tube mouth is sealed and the tube end is heat sealed. The applicator tip is designed to be twisted down on the tube mouth to puncture an opening. The cap is not removed. The tubes are constructed of Huntsman P5M6K-048 polypropylene, frosted white and have 0.0185" wall thickness. The applicator tips are constructed of Kepital F30-03 Acetal. The tube is the child-resistant feature. There are five package presentations; the small tube size (2 mL) contains either a 0.50 mL, 0.67 mL or 1.34 mL fill volume, the large tube size (7.8 mL) contains either a 2.68 mL or 4.02 mL fill volume. The tubes come in packages of three.

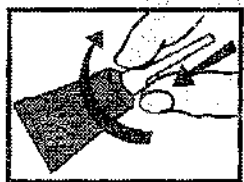
The tube has no instructions for opening the package. The opening instructions given to seniors during CRP testing were in the addendum of the Senior Adult Use Effectiveness (SAUE) studies. Seniors were

provided the outer carton of the packaging and asked to "Please open one of these [three] packages according to the instructions on this product carton and empty the contents into this tub/bucket". The outer carton of the packaging had the following instructions (from MRID 486846-01):

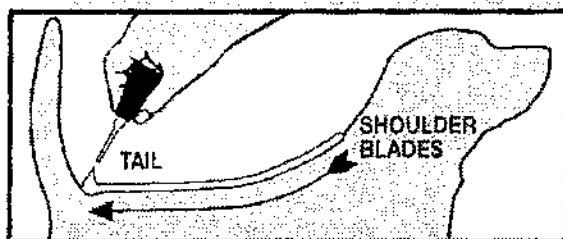
"...hold [applicator tube] in an upright position pointed away from your face. Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip".



① Remove one applicator tube from the package and hold in an upright position pointed away from your face.



② Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



③ Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

④ Repeat every month.

TOXICITY:

The toxicity of the product is based on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is 28.5 mg [2.5 mg/kg (per MRID 44431801) x 11.4 kg (per 16 CFR 1700.20) = 28.5 mg].

Access to a toxic or harmful amount for the Fipronil-only products EPA File Symbols: 2596-RAG and -RAU is 0.29 mL [28.5 mg / [1004 mg/mL x 0.097 Fipronil] = 0.293 ml = 0.29 mL].

Access to a toxic or harmful amount for the Fipronil and (S)-Methoprene dog product EPA File Symbol: 2596-RAL is 0.29 mL [28.5 mg / [999 mg/mL x 0.098 Fipronil] = 0.291 ml = 0.29 mL].

Access to a toxic or harmful amount for the Fipronil and (S)-Methoprene cat product EPA File Symbol: 2596-RAA is 0.29 mL [28.5 mg / [992 mg/mL x 0.098 Fipronil] = 0.293 ml = 0.29 mL].

Access to one tube represents a failure (toxic/harmful amount) for a child at all proposed fill sizes of 0.29 mL or larger for EPA File Symbols: 2596-RAG, -RAU, -RAL and -RAA, which are all proposed for residential use.

Toxicity, Child Failure, and Package

Table 1. Amount of Fipronil Contained in Proposed Products 2596-RAG, -RAU, -RAL and -RAA						
EPA Reg #	Fl. Oz.	ml (29.6 ml = 1 fl.oz)	Product Density* (mg/ml)	% Fipronil	mg Fipronil	# unit = tox / harmful amt
2596-RAG Dog Fipronil	0.023	0.67	1004	9.70	66.22	1
2596-RAG Dog Fipronil	0.045	1.34	1004	9.70	130.50	1
2596-RAG Dog Fipronil	0.091	2.68	1004	9.70	261.00	1
2596-RAG Dog Fipronil	0.136	4.02	1004	9.70	391.50	1
2596-RAU Cat Fipronil	0.017	0.50	1004	9.70	48.69	1
2596-RAL Dog Fipronil and (S)- Methoprene	0.023	0.67	999	9.80	66.57	1
2596-RAL Dog Fipronil and (S)- Methoprene	0.045	1.34	999	9.80	131.19	1
2596-RAL Dog Fipronil and (S)- Methoprene	0.091	2.68	999	9.80	262.38	1
2596-RAL Dog Fipronil and (S)- Methoprene	0.136	4.02	999	9.80	393.57	1
2596-RAA Cat Fipronil and (S)- Methoprene	0.017	0.50	992	9.80	48.61	1

* Presented as pounds (lbs) per gallon (gal) on CSFs. Product lbs/gal x [1 gal/3785 mL] x [454000 mg/1 lbs] = Product mg/mL

^a 1 mL = 0.0338 fl. oz

^b 1 fl. oz. = 29.6 mL

FAILURE:

For the purposes of CRP testing a **child failure** is access to 1 unit.

A **unit failure** is opening the tube, any visible incision, rip, tear, or hole in the tubes, any leakage during or after test or any partial or complete access to the placebo (water).

A **Senior Adult Use Effectiveness failure** is failure to access the tube contents in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, not accessing the tube contents without significant exposure to the placebo (water).

ANALYSIS OF DATA:

The registrant has submitted Senior Adult Use Effectiveness (SAUE) and Child-Resistant Effectiveness (CRE) data for EPA File Symbols: 2596-RAG, -RAU, -RAL, and -RAA. Each study contains both the SAUE and CRE data for a specific fill volume.

A screening of the CRP studies (MRIDs 486846-01 through -05) revealed the CRP study associated with the lowest SAUE was MRID 486846-01 (NCRT Job#: 11-051), a 2 mL tube size containing 0.5 mL of placebo in 3-tube package. The screening also revealed that the CRP study associated with the lowest CRE was MRID 486846-04 (NCRT Job#: 11-060), a 7.8 mL tube size containing 2.68 mL of placebo in a 3-tube package. A comprehensive review was done for these studies, which included their corresponding CRE and SAUE data, respectively.

A cursory analysis of data with confirmation of information provided in the submitted reports was performed for the remaining studies. Please see attached summary chart for details of these studies (Attachment A).

Detailed Reviews:

EPA File Symbols: 2596-RAU, -RAA:

0.5 mL Fill Volume

- The registrant is requesting registration of a 3-tube per package presentation; a SAUE/CRE study was submitted (MRID 486846-01, NCRT Job#: 11-051).

SAUE: The study involved handing the test subjects 3 applicator tubes filled with 0.5 mL of water for each of 2 test periods. The test subjects were to open one tube during a 5-minute test period and another tube during a one-minute test period. Directions to open the package were provided to seniors.

Data Analysis: Senior ages, gender distributions, age allocations, as well as test site and tester requirements all adhered to the senior testing regulations set forth in 16 CFR 1700.20. There were 9 senior failures: a) a 55 year old female, b) a 60 year old female, c) a 62 year old female, d) a 63 year old female, and e) two 67 year old females failed to successfully open a tube in the first 5-minute test period; and f) another 55 year old female, g) another 63 year old female, and g) a 66 year old female failed to successfully open a tube during the 1-minute test period. This corresponds to a 91% SAUE success rate. The study (MRID 486846-01) is considered as "passing" the senior test according to 16 CFR 1700.20.

CRE: The study involved giving each child 3 applicator tubes filled with 0.5 mL of water at the start of the test. Directions did not appear on any of the test packages. Procedures followed 16 CFR 1700.20(a)(2); all verbal instructions given to the children are contained in the stated citation.

Data Analysis: Child ages, gender distributions, age allocations, as well as test site and tester requirements all adhered to the child testing regulations set forth in 16 CFR 1700.20. There were 3 child failures (50 child test); a) a 45 month old female, b) a 47 month old male, and c) a 50 month old female each opened a single tube (chewed a hole in the tube) within the full 10 minutes of testing, after demonstration. This corresponds to a 94% CRE. The study (MRID 486846-01) is considered as "passing" the child test according to the sequential test chart in 16 CFR 1700.20.

Conclusion: Both senior SAUE and child CRE testing data requirements have been fulfilled for the 2 mL tube size, 0.5 mL fill volume, 3-tube package presentations for EPA File Symbols: 2596-RAU and -RAA.

EPA File Symbols: 2596-RAG, -RAL:

2.68 mL Fill Volume

- The registrant is requesting registration of a 3-tube per package presentation; a SAUE/CRE study was submitted (MRID 486846-04, NCRT Job#: 11-060).

SAUE: The study involved handing the test subjects 3 applicator tubes filled with 2.68 mL of water for each of 2 test periods. The test subjects were to open one tube during a 5-minute test period and another tube during a one-minute test period. Directions to open the package were provided to seniors.

Data Analysis: Senior ages, gender distributions, age allocations, as well as test site and tester requirements all adhered to the senior testing regulations set forth in 16 CFR 1700.20. There were 6 senior failures: a) a 59 year old female, b) a 60 year old female, c) a 64 year old female, d) a 67 year old female, and e) a 68 year old females failed to successfully open a tube in the first 5-minute test period; and f) a 55 year old female failed to successfully open a tube during the 1-minute test period. This corresponds to a 94% SAUE success rate. The study (MRID 486846-04) is considered as "passing" the senior test according to 16 CFR 1700.20.

CRE: The study involved giving each child 3 applicator tubes filled with 2.68 mL of water at the start of the test. Directions did not appear on any of the test packages. Procedures followed 16 CFR 1700.20(a)(2); all verbal instructions given to the children are contained in the stated citation.

Data Analysis: Child ages, gender distributions, age allocations, as well as test site and tester requirements all adhered to the child testing regulations set forth in 16 CFR 1700.20. There were 5 child failures (50 child test); a) a 43 month old female and b) a 51 month old male each opened a single tube (chewed a hole in the tube), while c) a 49 month old male, d) a 49 month old female and e) a 51 month old male each opened multiple tubes (chewed hole in the tubes), within the full 10 minutes of testing, after demonstration. This corresponds to a 90% CRE. The study (MRID 486846-04) is considered as "passing" the child test according to the sequential test chart in 16 CFR 1700.20.

Conclusion: Both child CRE and senior SAUE CRP testing data requirements have been fulfilled for the 7.8 mL tube size, 2.68 mL fill volume, 3-tube package presentation for EPA File Symbols: 2596-RAG and -RAL.

CONCLUSION: Based on the submitted data reviewed herein, all SAUE and CRE CRP testing data requirements have been met for the 3-tube package presentations for the 0.67 mL fill volume, the 1.34 mL fill volume, the 2.68 mL fill volume and the 4.02 mL fill volume for EPA File Symbols 2595-RAG, -RAL; as well as the 3-tube presentations for the 0.5 mL fill volume for EPA File Symbol 2595-RAU and -RAA. The data support production with Huntsman P5M6K-048 polypropylene, frosted white tubes with 0.0185" wall thickness, only. All CRP Certifications for the aforementioned products are acceptable. The labels submitted (email to B. Hanson and R. Gross, label revision date 27/MAR/2012) have the same instructions used in the SAUE testing. See the attached summary chart (Attachment A) for a summary of all currently reviewed SAUE and CRE CRP testing data.

Note to Registrant: Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

SUMMARY CHART

EPA File Symbols 2596-RAG, -RAU, -RAL, -RAA

Company: The Hartz Mountain Corporation

Chemical - Fipronil or Fipronil and S-Methoprene

A **Senior Adult Use Effectiveness failure** is failure to access the tube contents in the prescribed test time of 5 minutes for the first package or 1 minute for the second package, not accessing the tube contents without significant exposure to the placebo (water).

A **child failure** is access to 1 unit. Access to 1 unit is more than 28.5 mg of Fipronil for all sizes greater than 0.29 ml.

A **unit failure** is opening the tube, any visible incision, rip, tear, or hole in the tube, any leakage during or after test, as well as any partial or complete access to the placebo (water).

Access to a toxic or harmful amt =

= 28.5 mg divided by [1004 mg/ml x 0.097 Fipronil] = **0.29 ml for Fipronil Only Dog and Cat**; EPA File Symbols 2595-RAG, -RAU

= 28.5 mg divided by [999 mg/ml x 0.098 Fipronil] = **0.29 ml for Fipronil and (S)-Methoprene Dog**; EPA File Symbol: 2596-RAL

= 28.5 mg divided by [992 mg/ml x 0.098 Fipronil] = **0.29 ml for Fipronil and (S)-Methoprene Cat**; EPA File Symbol: 2596-RAA

Toxicity, Child Failure, and Package**Table 1. Amount of Fipronil Contained in Proposed Products 2596-RAG, -RAU, -RAL and -RAA**

EPA Reg #	Fl. Oz.	ml (29.6 ml = 1 fl.oz)	Product Density* (mg/ml)	% Fipronil	mg Fipronil	# unit = tox / harmful amt
2596-RAG Dog Fipronil	0.023	0.67	1004	9.70	66.22	1
2596-RAG Dog Fipronil	0.045	1.34	1004	9.70	130.50	1
2596-RAG Dog Fipronil	0.091	2.68	1004	9.70	261.00	1
2596-RAG Dog Fipronil	0.136	4.02	1004	9.70	391.50	1
2596-RAU Cat Fipronil	0.017	0.50	1004	9.70	48.69	1
2596-RAL Dog Fipronil and (S)-Methoprene	0.023	0.67	999	9.80	66.57	1
2596-RAL Dog Fipronil and (S)-Methoprene	0.045	1.34	999	9.80	131.19	1
2596-RAL Dog Fipronil and (S)-Methoprene	0.091	2.68	999	9.80	262.38	1
2596-RAL Dog Fipronil and (S)-Methoprene	0.136	4.02	999	9.80	393.57	1
2596-RAA Cat Fipronil and (S)-Methoprene	0.017	0.50	992	9.80	48.61	1

* Presented as pounds (lbs) per gallon (gal) on CSFs. Product lbs/gal x [1 gal/3785 mL] x [454000 mg/1 lbs] = Product mg/mL; 1 mL = 0.0338 fl. oz; 1 fl. oz. = 29.6 mL

EPA File Symbol	MRID Study No.	PKG Description Include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Tubes/ Pkg.	Company Data		Data		Conclusion
				CRE	SAUE	Comprehensive Review/Why	Cursory Analysis	
2596 -RAU, -RAA	48684601 CRE 11-051	3 tubes @ a 2 ml size tube with 0.5 mL (placebo/product)	3 tubes	3 child failures (50 child test) = pass		X Lowest Associated CRE		Please see review, above.
2596 -RAU, -RAA	48684601 SAUE 11-051	3 tubes @ a 2 ml size tube with 0.5 mL (placebo/product)	3 tubes		9 senior failures = pass	X Lowest SAUE		Please see review, above.
2596 -RAG, -RAL	48684602 CRE 11-052	3 tubes @ a 2 ml size tube with 0.67 mL (placebo/product)	3 tubes	3 child failures (50 child test) = pass			X	Data analysis showed 3 child failures; a) a 43 month old male and b) a 44 month old male both squeezed the tube with their hands cracking open the sides of the tubes before and after demonstration, respectively, while c) a 49 month old male chewed a hole in the tubes after demonstration. NOTE: One child opened more than 1 tube. CRE = 94%. The study passes according to the Sequential Test Chart in 16 CFR 1700.20
2596 -RAG, -RAL	48684602 SAUE 11-052	3 tubes @ a 2 ml size tube with 0.67 mL (placebo/product)	3 tubes		6 senior failures = pass		X	Data analysis showed 6 senior failures; a) 55 year old female, b) a 57 year old male, c) a 68 year old female and d) a 69 year old female all failed to open the package in the 5-minute test period while a e) 66 year old male and f) 69 year old female failed to open the package during the 1-minute test. SAUE = 94%. The study is a pass of the senior adult test in 16 CFR 1700.20 and the effectiveness specifications in 16 CFR 1700.15(b).
2596 -RAG, -RAL	48684603 CRE 11-053	3 tubes @ 2 ml size tube with 1.34 mL (placebo/product)	3 tubes	4 child failures (50 child test) = pass			X	Data analysis showed 4 child failures; a) a 42 month old female squeezed water out of the tube end with her hands post-demonstration while b) a 45 month old female, c) a 48 month old female and d) a 48 month old male all chewed holes in tubes post-demonstration. CRE = 92%. The study passes according to the Sequential Test Chart in 16 CFR 1700.20

EPA File Symbol	MRID Study No.	PKG Description Include ml per Pkg	# Tubes	Company Data		Data		Conclusion
				CRE	SAUE	Comprehensive Review/Why	Cursory Analysis	
		# unit/pkg, child fail = # units, color, tox/harm = # units	# Tubes/Pkg.					include CRE & SAUE via computer analysis
2596 -RAG, -RAL	48684603 SAUE 11-053	3 tubes @ 2 ml size tube with 1.34 mL (placebo/product)	3 tubes		7 senior failures = pass		X	Data analysis showed 7 senior failures; a) a 59 year old female, b) a 60 year old female, c) a 65 year old male and d) a 66 year old female a 67 year old male failed to open a single tube during the first 5-minute test while e) a 62 year old female, f) a 63 year old female and g) a 67 year old female failed to open the package during the 1-minute test. SAUE = 93%. The study is a pass of the senior adult test in 16 CFR 1700.20 and the effectiveness specifications in 16 CFR 1700.15(b).
2596 -RAG, -RAL	48684604 CRE 11-060	3 tubes @ 7.8 ml size with 2.68 ml (placebo/product)	3 tubes	5 child failures (50 child test) = pass		X Lowest CRE		Please see review, above.
2596 -RAG, -RAL	48684604 SAUE 11-060	3 tubes @ 7.8 ml size with 2.68 mL (placebo/product)	3 tubes		6 senior failures = pass	X Lowest Associated SAUE		Please see review, above.
2596 -RAG, -RAL	48684605 CRE 11-061	3 tubes @ 7.8 ml size with 4.02 mL (placebo/product)	3 tubes	4 child failures (50 child test) = pass			X	Data analysis showed 4 child failures; a) a 44 month old male and b) a 45 month old female both pushed the applicator tip down and broke the seal post-demonstration while c) a 45 month old male and d) a 47 month old male chewed a hole in the tubes prior to demonstration. NOTE: 2 children opened more than 1 tube, CRE = 92%. The study passes according to the Sequential Test Chart in 16 CFR 1700.20
2596 -RAG, -RAL	48684605 SAUE 11-061	3 tubes @ 7.8 ml size with 4.02 ml (placebo/product)	3 tubes		2 senior failures = pass		X	Data analysis showed 2 senior failures; two 69 year old females failed to open the package in the 1-minute test period. SAUE = 98%. The study is a pass of the senior adult test in 16 CFR 1700.20 and the effectiveness specifications in 16 CFR 1700.15(b).



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 25, 2012

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 19-JAN-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

January 18, 2012

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM #10)

RE: HARTZ REF #128, EPA Reg. No. 2596-RAG
HARTZ REF #129, EPA Reg. No. 2596-RAU
HARTZ REF #130, EPA Reg. No. 2596-RAL
HARTZ REF #131, EPA Reg. No. 2596-RAA

**SUBMISSION OF AMENDED CHILD RESISTANT PACKAGE
TESTING**

Dear Mr. Gebken,

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting the amended Child Resistant Package Testing Reports for the above listed products. There are five reports (three copies of each), one covering each of the five dosages and we have also included a summary report for all five studies. The attached transmittal document identifies which studies support the above registrations.

The reports were amended to address the deficiencies that were identified in the EPA letter dated December 16, 2011. We have added the Statement of Compliance with Good Laboratory Practices Standards and the Statement of Data Confidentiality Claims to all reports. I have also included copies of my original cover letter, the Child Resistant Packaging Certification Statement and the Transmittal Document (including the MRID numbers assigned by EPA).

If you have any questions or require additional information, please contact me at 201-271-4800, ext 7302 or smcnear@hartz.com.

Sincerely,

Sean McNear
Director Regulatory Affairs

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 16, 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 30-NOV-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

48684601- 48684606

* You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

48684601- 48684605

* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 2, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

LANCE HEMSARTH
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

PRODUCT NAME: HARTZ REFERENCE #130
COMPANY NAME: THE HARTZ MOUNTAIN CORPORATION
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 2596-RAL
EPA RECEIPT DATE: 05/01/12

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely,

A handwritten signature in black ink, appearing to be "S. J. A." or similar, written over a horizontal line.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{916103n~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 10

Receipt No.

S-

916103

EPA File Symbol/Reg. No.

2596-RAL

Pin-Punch Date:

4/30/2012

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer:

[Signature]

Date:

5/2/12

Remarks:

Resubmission

Receipt for Section 3

S: 516103

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Pending Product Amendment

Billable: ☒ Yes ☐ No

Company: 2596 THE HARTZ MOUNTAIN CORPORATION

V

Risk Manager: Registration Division, Risk Management Team 10

Product #: 2596-RAL Product Name: HARTZ REFERENCE #130

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 27 Apr-2012

ie

OPP Rec'd Date: 01 May-2012

ie

Front End Date: 01 May-2012

ie

Risk Manager Send Date:

ie

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label Amendment

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Paper Label

View/Edit



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

April 27, 2012

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Richard Gebken (PM # 10)**

**RE: HARTZ REF #128, EPA Reg. No. 2596-RAG
 HARTZ REF #129, EPA Reg. No. 2596-RAU
 HARTZ REF #130, EPA Reg. No. ~~2596-RAU~~
 HARTZ REF #131, EPA Reg. No. 2596-RAA**

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing modified labels based on the feedback from Rosalind Gross and her review of the CRP data for the above listed registrations. Changes were made only to the directions for use sections in order to match the instructions for use in the child resistant packaging testing labels.

These master labels replace the current labels that were submitted for the above listed registrations. Please find enclosed 3 copies of each Master Label.

If you have any questions or need any additional information, please feel free to call me at (201) 271-4800, ext. 7302 or smcneear@hartz.com.

Sincerely,

Sean McNear
Director Regulatory Affairs

Enclosures



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-RAL	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Hartz Ref. 130	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive, Secaucus, NJ 07094 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Label change based on the feedback from Rosalind Gross. Changes made to the master label directions for use to be exactly the same as the instructions for the child resistant packaging (CRP) test.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
5. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Sean McNear	Title Director Reg. Affairs	Telephone No. (Include Area Code) 201-271-4800
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamp)
2. Signature 	3. Title Director Regulatory Affairs	
4. Typed Name Sean McNear	5. Date April 27, 2012	

Hartz® Reference # 130

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Dogs

Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® Pro Force™ Dual Action Topical Treatment for Dogs
Hartz® FieldForce™ Dual Action Topical Treatment for Dogs
Hartz® First Defense™ Dual Action Topical Treatment for Dogs

Hartz® Pro Force™ for Dogs
Hartz® FieldForce™ for Dogs
Hartz® First Defense™ for Dogs

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Dogs
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FieldForce™ Dual Action Topical Treatment for Dogs
First Defense™ Dual Action Topical Treatment for Dogs
FieldForce™ for Dogs
First Defense™ for Dogs

FieldForce™ Dual Action Topical Solution for Dogs
First Defense™ Dual Action Topical Solution for Dogs

[Each of the above brands will be packaged in the weight classes designated below:]

Weighing Up to 22 lbs.
Weighing 23 to 44 lbs.
Weighing 45 to 88 lbs.
Weighing 89 - 132 lbs.

ACTIVE INGREDIENTS:

Fipronil.....9.80%
(S)-Methoprene.....8.80%

OTHER INGREDIENTS 81.40%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains (number) tubes, each __ fl. oz. (__ ml)

For Dogs and Puppies Weighing:	Net Contents (Each tube)
Up to 22 lbs.	0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.136 fl. oz. (4.02 ml.)

EPA Reg. No. 2596-RAL
EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panels, and possibly an additional placement on a side panel.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few

days of application, consult a veterinarian immediately. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

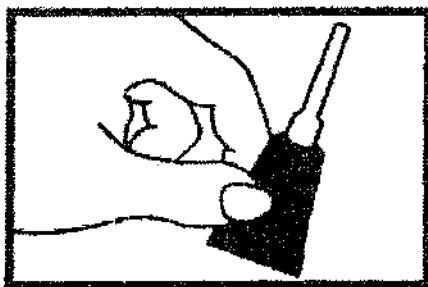
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

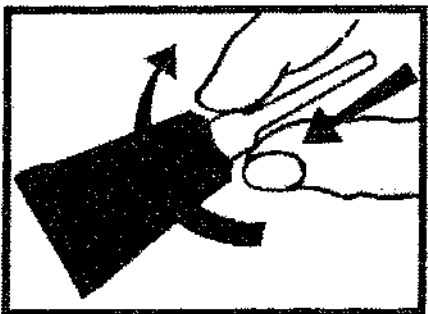
READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER

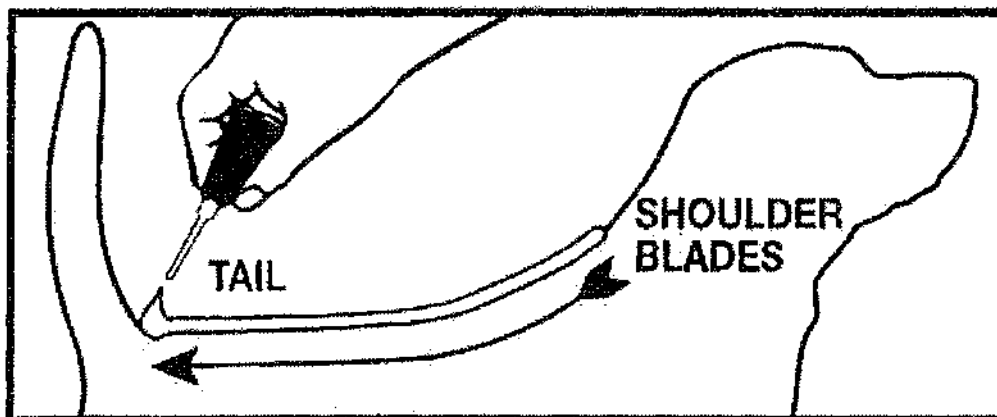
THIS PRODUCT IS APPROVED FOR USE ON ALL DOGS, INCLUDING BREEDING, PREGNANT AND LACTATING BITCHES



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



3 Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

4 Repeat every month.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

[Product name will be followed by weight of dog for which tube is intended]

[A duplicate weight class designation may be printed on the tube]

Active Ingredients:

Fipronil 9.8%, S-Methoprene 8.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

[Range of volumes from 0.023 fl. oz. (.67 ml) to 0.136 fl. oz (4.02 ml) depending upon weight of dog]

EPA Reg. No. 2596-RAL

EPA Est. No.

OPTIONAL/ALTERNATE LABEL TEXT

Weighing up to 22lbs lbs.

Weighing 23 - 44 lbs.

Weighing 45 - 88 lbs.

Weighing 89 - 132 lbs.

[Adult Fleas]

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills (Adult) Fleas (for up to 3 months)
Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on dogs)
Kills newly emerged adult Fleas before they lay eggs
If there is a high risk for flea reinfestation, a once a month application may be needed
Stops existing infestations
Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)
Kills all biting stages of ticks
Kills adult (brown dog) (deer) ticks, nymphs and larvae
Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents development of all flea stages for up to 3 months.
Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for dogs and puppies)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs)

Controls flea and tick infestations
Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)
(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control)
(Solution)
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)
Gentle protection for dogs (and puppies)
Quick drying (formula)
Dries quickly
Stays on and doesn't rub off
Spreads with dog's natural skin oils
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation
Prevents and controls re-infestation(s)
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Easy spot on topical applicator

Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Can also be used on breeding, pregnant and lactating bitches
Convenient to use
Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name)
effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles,
and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting
activity against fleas, ticks and chewing lice.

New (Formula) *(claim to be removed after 6 months)*

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus ®).
(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.

Compare to Frontline Plus®

For dogs and puppies 8 weeks of age or older
Specially formulated for dogs and puppies

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

Value pack

(X) month supply

(X) monthly treatment(s)

Fragrance-free

Unscented

Convenient (easy to use) applicator

X Pro-cision Flo® Applicator(s)

(Pro-cision Flo® Applicator)

Direct to your dog's skin

Easy (simple) to use (handle) (apply)

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your dog 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____

Second Dose _____

Third Dose _____

Xth Dose _____

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Hartz® Reference # 130

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Dogs
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FieldForce™ for Dogs
First Defense™ for Dogs

FieldForce™ Dual Action Topical Solution for Dogs
First Defense™ Dual Action Topical Solution for Dogs

[Each of the above brands will be packaged in the weight classes designated below:]

Weighing Up to 22 lbs.
Weighing 23 to 44 lbs.
Weighing 45 to 88 lbs.
Weighing 89 - 132 lbs.

ACTIVE INGREDIENTS:

Fipronil.....	9.80%
(S)-Methoprene.....	8.80%
OTHER INGREDIENTS	81.40%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains (number) tubes, each __ fl. oz. (__ ml)

For Dogs and Puppies Weighing:	Net Contents (Each tube)
Up to 22 lbs.	0.023 fl. oz. (0.67 ml.)
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45 - 88 lbs.	0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.136 fl. oz. (4.02 ml.)

EPA Reg. No. 2596-RAL
EPA Est. No.

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Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panels, and possibly an additional placement on a side panel.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few

days of application, consult a veterinarian immediately. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

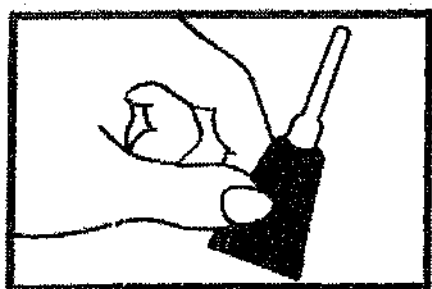
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

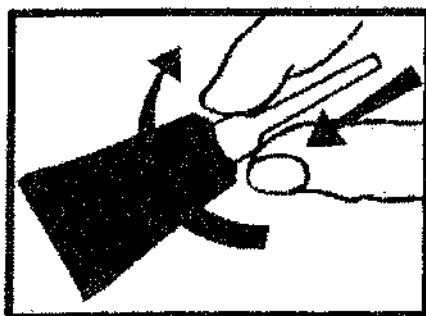
READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER

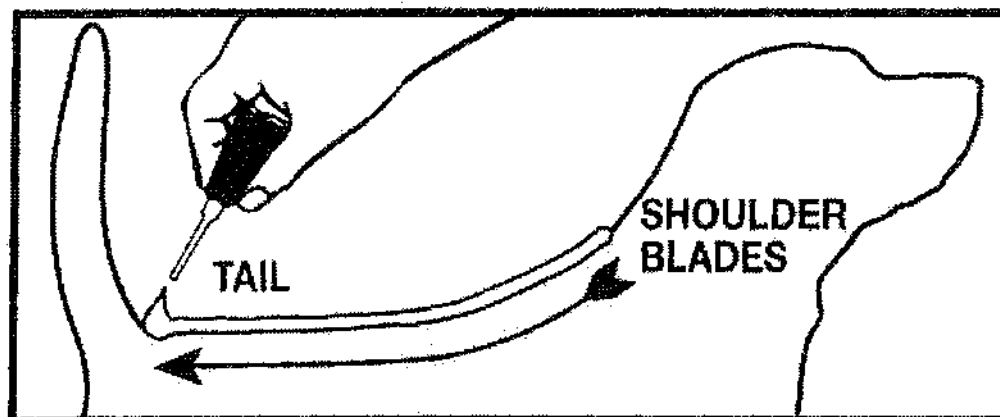
THIS PRODUCT IS APPROVED FOR USE ON ALL DOGS, INCLUDING BREEDING, PREGNANT AND LACTATING BITCHES



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about $\frac{1}{2}$ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



3 Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

4 Repeat every month.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am -- 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

[Product name will be followed by weight of dog for which tube is intended]

[A duplicate weight class designation may be printed on the tube]

Active Ingredients:

Fipronil 9.8%, S-Methoprene 8.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

[Range of volumes from 0.023 fl. oz. (.67 ml) to 0.136 fl. oz (4.02 ml) depending upon weight of dog]

EPA Reg. No. 2596-RAL

EPA Est. No.

OPTIONAL/ALTERNATE LABEL TEXT

Weighing up to 22lbs lbs.

Weighing 23 - 44 lbs.

Weighing 45 - 88 lbs.

Weighing 89 - 132 lbs.

[Adult Fleas]

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks) (61 dogs)

Kills (Adult) Fleas (for up to 3 months)
Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on dogs)
Kills newly emerged adult Fleas before they lay eggs
If there is a high risk for flea reinfestation, a once a month application may be needed
Stops existing infestations
Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)
Kills all biting stages of ticks
Kills adult (brown dog) (deer) ticks, nymphs and larvae
Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Prevents development of all flea stages for up to 3 months.
Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for dogs and puppies)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations
Kills all stages of the flea life cycle
Breaks the flea life cycle
Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs)

Controls flea and tick infestations
Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)
(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)
Gentle protection for dogs (and puppies)
Quick drying (formula)
Dries quickly
Stays on and doesn't rub off
Spreads with dog's natural skin oils
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation
Prevents and controls re-infestation(s)
Rapidly eliminates fleas
Fast acting
Long lasting
Effective and convenient topical treatment
Kills fleas (and ticks) through (after) contact
(With) patented applicator
(With) patent pending applicator
Waterproof
Easy spot on topical applicator

Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Can also be used on breeding, pregnant and lactating bitches
Convenient to use
Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name) effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

New (Formula) (*claim to be removed after 6 months*)

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus ®).
(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered trademark of Merial.

Compare to Frontline Plus®

For dogs and puppies 8 weeks of age or older
Specially formulated for dogs and puppies

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)

First month, second month, third month (Xth month)

Value pack

(X) month supply

(X) monthly treatment(s)

Fragrance-free

Unscented

Convenient (easy to use) applicator

X Pro-cision Flo® Applicator(s)

(Pro-cision Flo® Applicator)

Direct to your dog's skin

Easy (simple) to use (handle) (apply)

After application, the treated area may appear wet (or) (oily) for up to 24 hours

You may bathe your dog 48 hours after application

To help remind you when you last applied treatment, simply write in the date when each dose is applied:

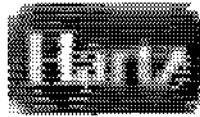
First Dose _____

Second Dose _____

Third Dose _____

Xth Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation



48684600

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

November 29, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM #10)

**RE: HARTZ REF #128, EPA Reg. No. 2596-RAG
HARTZ REF #129, EPA Reg. No. 2596-RAU
HARTZ REF #130, EPA Reg. No. 2596-RAL
HARTZ REF #131, EPA Reg. No. 2596-RAA**

SUBMISSION OF CHILD RESISTANT PACKAGE TESTING

Dear Mr. Gebken,

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting the Child Resistant Package Testing Reports for the above listed products. There are five reports (three copies of each), one covering each of the five dosages and we have also included a summary report for all five studies. The attached transmittal document identifies which studies support the above registrations.

The submission of these reports should complete the registration requirements for the above listed products.

If you have any questions or require additional information, please contact me at 201-271-4800, ext 7302 or smcnear@hartz.com.

Sincerely,

Sean McNear
Director Regulatory Affairs

Enclosure



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

CHILD RESISTANT PACKAGING CERTIFICATION STATEMENT
Title 40 part 157 subpart B

Registrant Name and Address:

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Products:

Hartz Reference # 128, EPA Reg. No. 2596-RAG
Hartz Reference # 129, EPA Reg. No. 2596-RAU
Hartz Reference # 130, EPA Reg. No. 2596-RAL
Hartz Reference # 131, EPA Reg. No. 2596-RAA

I certify that the packaging that will be used for the products listed above meet the standards of 40 CFR 157.32.

A handwritten signature in black ink, appearing to read "Sean McNear". The signature is fluid and cursive, written over a horizontal line.

Sean McNear
Director Regulatory Affairs

A handwritten date in black ink, "November 29, 2011", written over a horizontal line.

Date

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094

2. REGULATORY ACTION IN SUPPORT OF WHICH THESE PACKAGES ARE SUBMITTED

Submission of Child Resistant Packaging Testing Reports:

Fipronil; Hartz Reference #128, EPA File Symbol 2596-RAG

Fipronil; Hartz Reference #129, EPA File Symbol 2596-RAU

Fipronil and (S)-Methoprene; Hartz Reference #130, EPA File Symbol 2596-RAL

Fipronil and (S)-Methoprene; Hartz Reference #131, EPA File Symbol 2596-RAA

3. TRANSMITTAL DATE November 29, 2011

4. LIST OF SUBMITTED DOCUMENTS

3684601 VOLUME 1 Child Resistant Package Test Final Report (3 copies)
NCRT Job # 11-051
Fill Volume 0.5 mL

For Hartz Ref. # 129, EPA Reg. No. 2596-RAU
For Hartz Ref. # 131, EPA Reg. No. 2596-RAA

8684602 VOLUME 2 Child Resistant Package Test Final Report (3 copies)
NCRT Job # 11-052
Fill Volume 0.67 mL

For Hartz Ref. # 128, EPA Reg. No. 2596-RAG
For Hartz Ref. # 130, EPA Reg. No. 2596-RAL

1684603 VOLUME 3 Child Resistant Package Test Final Report (3 copies)
NCRT Job # 11-053
Fill Volume 1.34 mL

For Hartz Ref. # 128, EPA Reg. No. 2596-RAG
For Hartz Ref. # 130, EPA Reg. No. 2596-RAL

3684604 VOLUME 4 Child Resistant Package Test Final Report (3 copies)
NCRT Job # 11-060
Fill Volume 2.68 mL

For Hartz Ref. # 128, EPA Reg. No. 2596-RAG
For Hartz Ref. # 130, EPA Reg. No. 2596-RAL

Child Resistant Package Test Final Report (3 copies)
NCRT Job # 11-061
Fill Volume 4.02 mL

8684606 VOLUME 6

Child Resistant Package Test Summary Report (3 copies)
Fill Volumes 0.5 mL; 0.67mL; 1.34 mL; 2.68 mL; 4.02 mL

For Hartz Ref. # 129, EPA Reg. No. 2596-RAU
For Hartz Ref. # 131, EPA Reg. No. 2596-RAA
For Hartz Ref. # 128, EPA Reg. No. 2596-RAG
For Hartz Ref. # 130, EPA Reg. No. 2596-RAL

Child Resistant Packaging Certification Statement (3 copies)

ADMIN

For Hartz Ref. # 129, EPA Reg. No. 2596-RAU
For Hartz Ref. # 131, EPA Reg. No. 2596-RAA
For Hartz Ref. # 128, EPA Reg. No. 2596-RAG
For Hartz Ref. # 130, EPA Reg. No. 2596-RAL


5. COMPANY OFFICIAL Sean McNear, Director Regulatory Affairs

6. SIGNATURE

Sean McNear

7. PHONE 201-271-4800, ext. 7302

Decision Information for 2596-RAL

Decision Seq: 445034	Action Code: R310 (NEW PRODUCT, NON-FAST TRACK (INCLUDES REVIEWS D ...	Decision Status
FFS Start Date: 08-Mar-2011	Tentative Ind: No	Tracking
Due Date: 08-Sep-2011	75-Day Due Date:	Create Resubmission
OPP Target Due Dt:	21-Day Screen Dt: 08-Mar-2011	FFS Letters
Negotiated Due Dt: 08-Mar-2012	Start/Stop Clock: F/GPA Clock:	FFS Primary Decision:
Registrant: 	Days Elapsed:	Action Code History
Response Due Date:		Secondary Decision
Current Status: PENDING (15-Jul-2011)		

- | | | | |
|---|---|--|---|
|  Decision Comments |  Payment |  Unmatched Payments |  75 Day Letters |
|  Meetings & Milestones |  FFS Information |  FFS Negotiated Due Dates |  OPP Target Due Date |
|  Decision Ownership |  Receipts |  Data Package |  Reduced Risk |

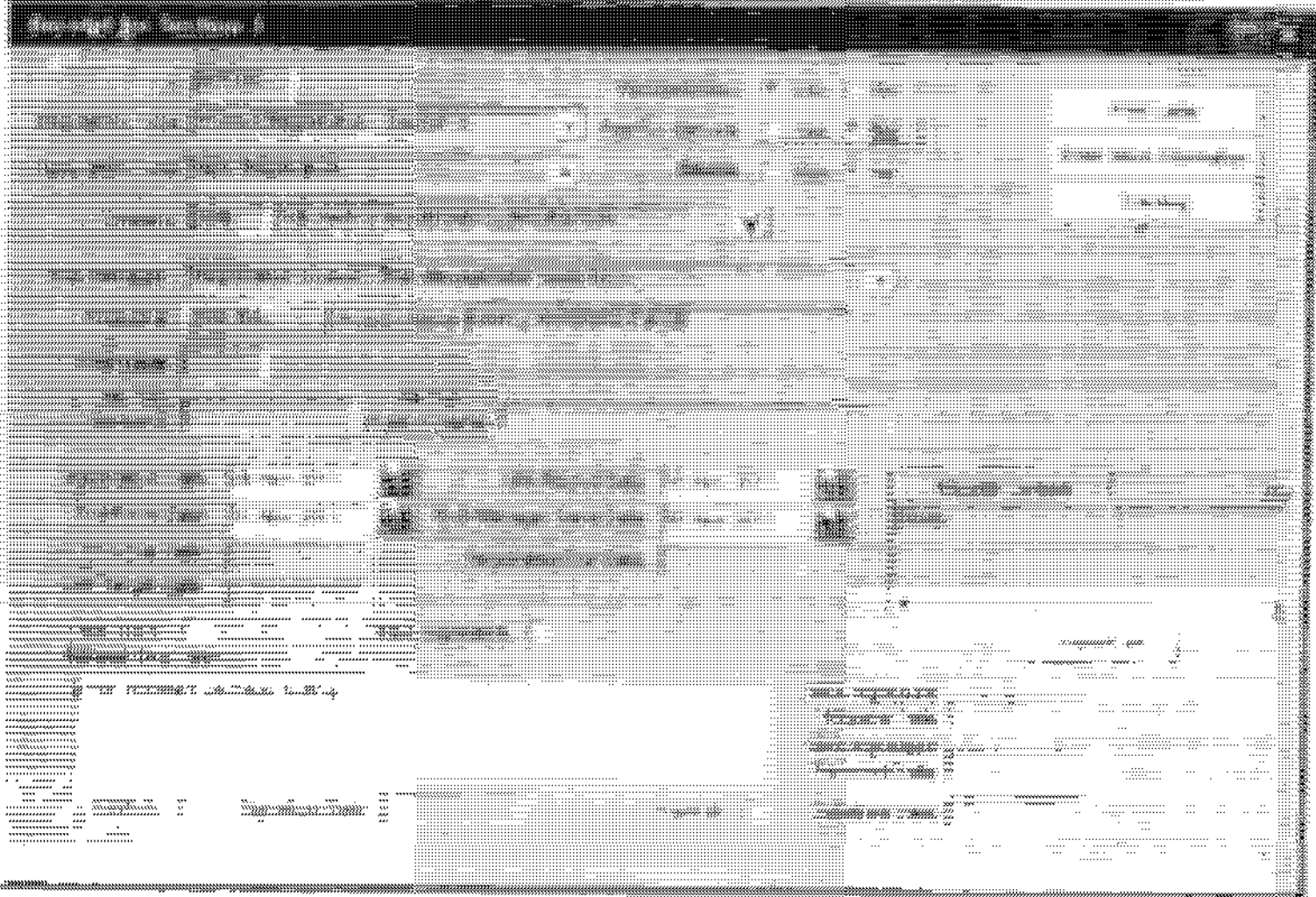
Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S 911978	Akinlosotu, Bonaventure	2596-RAL	08-Mar-2012	PENDING
Amended CRP for CRP Testing				
S 907614	Akinlosotu, Bonaventure	2596-RAL	08-Mar-2012	PENDING
Resubmission of revised Data Matrix				
S 901778	Akinlosotu, Bonaventure	2596-RAL	08-Mar-2012	GENERAL RESPONSE TO APPLI
Addendum to Existing Protocol for CRP				
S 901778	Akinlosotu, Bonaventure	2596-RAL	08-Mar-2012	PENDING


Viewing Record 1 of 1

Received

2/21/2012

BA



 <p align="center">ENVIRONMENTAL PROTECTION AGENCY</p> <p align="center">Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p>	EPA Registration No. <p align="center">2596-165</p>	Date of Issuance: <p align="center">July 9, 2012</p>
<p align="center">NOTICE OF PESTICIDE:</p> <p align="center"><input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration</p> <p align="center">(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>	Term of Issuance: <p align="center">Unconditional</p> Name of Pesticide Product: <p align="center">Hartz @ Reference # 130</p>	
<p>Name and Address of Registrant (include ZIP Code):</p> <p>The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094</p> <p>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</p>		
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p>This action is taken under the authority of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.</p> <p align="center">Terms of Registration</p> <p>1. EPA has registered the product listed above provided that the following change is made to the label before you release the product for shipment:</p> <ol style="list-style-type: none"> Revise the EPA Registration Number to read: "EPA Registration No 2596-165." The Net Contents in all locations must be displayed in accordance with the description identified in the Labeling Consistency Committee's clarification. This information may be located at the following Agency web site under miscellaneous http://www.epa.gov/opp00001/regulating/labels/label_review_faq.htm#miscellaneous. "Regarding listing net contents - Net weight or contents must be stated on a pesticide label in accordance with FIFRA (2)(q)(2)(C)(iii) and 40 CFR 156.10(a)(1)(iii). EPA interpretation of the statutory and regulatory requirements is that the label must state the total weight for the entire contents as sold and distributed. In 		
Signature of Approving Official: <p align="center">Refer to Page 5</p> Richard J. Gebken, Product Manager (10) Registration Division, Insecticide Branch	Date: <p align="center">July 6, 2012</p>	

addition, the label may indicate the net weight and quantity of individual units within the carton. For example, "Net Weight 6.25 lbs. (20 - 5oz. packets)." For additional information regarding the Net Weight/Contents statement, please reference Chapter 17 of the Label Review Manual at <https://www.epa.gov/opptoad1/labeling/lrm/chap-17.htm>."

- c. Under the brand name "Hartz® Reference # 130" and any other alternate brand name, add the following statement "For use **ONLY** on **DOGS 8 weeks and older**" The word "DOG" the word "puppies 8 weeks and older" must be the same size as the brand name.
- d. The statement "[Cat Warning: A cat prohibition icon will appear on the front panel and back panels, and possibly an additional placement on a side panel.]" is inadequate. Specific locations for all Cat Warnings must be presented on the draft label for review of acceptability.
- e. **Pictures:** Hartz must place large, clear pictures of the appropriate species on the front panel.
- f. Revise the precautionary statements by replacing the sentence: "Harmful if swallowed," with "Harmful if swallowed or absorbed through the skin."
- g. Replace "Wash thoroughly with soap and water after handling," with "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet."
- h. Replace "Individual sensitivities, while rare, may occur after using any pesticide product." with "Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately."
- i. Remove "If signs persist, or become more severe within a few days of application, consult a veterinarian immediately." This statement is incorrect and has been incorporated as part of the sensitivity statement directly above.
- j. Replace "Consult a veterinarian before using on medicated, debilitated or aged animals." with "Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals."
- k. Replace the medical contact information statement at the top of the First Aid Section with :
"Have product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Hotline number 1-800-xxx-xxx for human and veterinary health concerns, emergency medical treatment information or pesticide incidents." The xxx-xxxx must be replaced with a phone number that is available 24/7.
- l. Revise the following statement : **THIS PRODUCT IS APPROVED FOR USE ON ALL DOGS, INCLUDING BREEDING, PREGNANT AND LACTATING BITCHES**" by replacing "IS APPROVED FOR USE ON ALL DOGS" with "**CAN BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER.**"
- m. Add the following statement directly after "I" described directly above: "**DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS.**"
- n. Replace "Repeat every month" with "Reapply once per month."
- o. **INDIVIDUAL TUBE TEXT:** Revise the Individual tube text as follows:

[Product Name]
Only for use on **DOGS AND PUPPIES 8 WEEKS OR OLDER**
[The appropriate size and fill volume will be correctly used on each applicable dog's weight category.]
Up to 22 lbs.- 0.023 fl. oz. (0.67 mL),
23 to 44 lbs.- 0.045 fl. oz. (1.34 mL),
45 – 88 lbs.- 0.091 fl. oz. (2.68 mL),
89 -132 lbs.- 0.136 fl. oz. (4.02 mL)
Contains fipronil (9.80%), (S)-Methoprene (8.80%)
KEEP OUT OF REACH OF CHILDREN
CAUTION
See full label for additional directions
EPA Reg. No. 2596-165

- p. Revise the statement: "Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)" by correcting the "(on dogs)" with "(on dogs and puppies 8 weeks of age or older)"
 - q. Revise the claims: "Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs)" and "Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs)" by correcting "(on dogs)" with "(on dogs and puppies 8 weeks of age or older)"
 - r. Revise "Kills (Adult) Fleas (for up to 3 months)" by removing "(for up to 3 months)"
 - s. Revise "Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on dogs)" by removing "(3 months)"
 - t. Revise the statement "Kills adult Fleas, Flea Eggs and Larvae (for up to three months)" by removing "(for up to three months)"
 - u. Revise the statement: "Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for dogs and puppies)" by adding "8 weeks or older" after "puppies".
 - v. Remove the word "also" from the marketing claim: "Can also be used on breeding, pregnant and lactating bitches"
 - w. Remove the following marketing claim: "Gentle protection for dogs and puppies)" This claim is an implied safety claim, and detracts from other mandatory precautionary label language on the label.
 - x. Remove the marketing claims "Quick drying (formula)", and "Dries quickly" These claims conflict with the statement: "After application, the treated area may appear wet (or) (oily) for up to 24 hours."
 - y. Remove the statement: "Spreads with dog's natural skin oils" The Agency's Labeling Consistency Committee has determined that this statement is false and misleading under 40CFR 156.10.
 - z. The marketing claim "New (formula)" is allowed for a period of 6 months from the date of this Notice of Registration.
 - aa. The product comparative claim must adhere to the Labeling Consistency Guidance document located at the following Agency web address: <http://www.epa.gov/pesticides/regulating/labels/pdf/metoo.pdf>.
 - bb. Revise the statement "For dogs and puppies 8 weeks of age or older." to: "Only for use on dogs and puppies 8 weeks of age or older."
 - cc. Revise the claim: "Specially formulated for dogs and puppies" to: "'Formulated for dogs and puppies 8 weeks of age or older."
 - dd. Replace the "(X)" in the following claims: "(X) month supply" and "(X) monthly treatment(s)" with a 3. This is the only package approved by CRP testing, and must be the only package size displayed on the label. Any other package design would require additional Child Resistant Packaging testing.
 - ee. Remove the statements: "Fragrance-free" and "Unscented" Claims about the Absence of an Ingredient: Statements or claims that express the absence of certain ingredients may be misleading statements prohibited by 40 CFR 156.10 (a)(5). These claims are examples of a true statement used in such a way as to give a false and misleading impression to the purchaser.
 - ff. Placement descriptors must be used on any future label submissions indicating the position of all text. (i.e. Front Panel, Insert, Back Panel, etc.). Future submissions will not be accepted unless these placement descriptors are identified on the label at time of submission.
 - gg. Within 30 days of this Notice of Registration, Hartz Mountain Corporation must revise the data matrix in accordance with the Companion Animal Safety Data Evaluation Report (DER) dated August 10, 2011. If the data matrix is not corrected, the claims and statements associated with this DER must be removed. In addition, there are incorrect studies cited in the data matrix for the Acute Toxicity of the product which needs to be corrected in the data matrix.
2. This registration is time-limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected "release for shipment date", in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.
 3. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product, except to allow for alternate sources of any individual inert ingredient).
 4. You must submit the following data within the timeframe described below:
Within sixteen (16) months of the date on this Notice of Registration, provide to the Agency acceptable data packages for Guideline Studies: OPPTS 830.6320 (Corrosion Characteristics) and OPPTS 830.6317 (Storage Stability).
 5. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1, 2012. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting

6. Page 4 of 5

should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot#
Where purchased: internet, store, Veterinarian
Active Ingredient(s)
Weight range for product
Date on which incident occurred, (mm/dd/yyyy)
State in which the incident occurred, (standard 2 letter abbreviation)
Registrant case #
Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds
Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other Major signs noted
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

7. Along with the enhanced incident reporting, you must submit an analysis of all incidents seen, to include the following details:
- All minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - Table showing number of incidents for each dog breed.
 - Table showing number of incidents in dogs for each clinical sign.
 - Table showing number of incidents in dogs for each organ system.
 - Report aggregate incidents, but do not combine moderate and minor incidents.
8. If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform all registrants concerned. If mitigation measures are necessary, EPA may take regulatory action.
9. Hartz Mountain Corporation must adequately address all of the mitigation actions identified in the Agency's *Generic Pet Spot-On Mitigation Plan* available at the following internet site within 60 days following the date of this Notice of Registration: <http://www.epa.gov/pesticides/health/spot-on-meetings.html>.

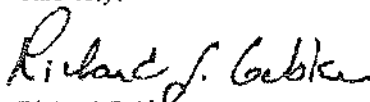
Page 5 of 6

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for registration review of your product under FIFRA.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact me Richard J. Gebken at (703) 305-6701 or gebken.richard@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Richard J. Gebken". The signature is written in a cursive style with a large, stylized "R" and "G".

Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505C)

Enclosure

Hartz® Reference # 129

Alternate Brand Names

Hartz® UltraGuard® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® InControl® Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Revo™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Revo™ Flea (and) (&) Tick Topical Treatment for Cats (& Kittens)

Hartz® Pro Force™ Topical Treatment for Cats (& Kittens)

Hartz® FieldForce™ Topical Treatment for Cats (& Kittens)

Hartz® First Defense™ Topical Treatment for Cats (& Kittens)

Hartz® UltraGuard® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® InControl® Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Revo™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® Revo™ Flea (and) (&) Tick Topical Solution for Cats (& Kittens)

Hartz® Pro Force™ Topical Solution for Cats (& Kittens)

Hartz® FieldForce™ Topical Solution for Cats (& Kittens)

Hartz® First Defense™ Topical Solution for Cats (& Kittens)

FieldForce™ Topical Treatment for Cats (& Kittens)

First Defense™ Topical Treatment for Cats (& Kittens)

FieldForce™ Topical Solution for Cats (& Kittens)

First Defense™ Topical Solution for Cats (& Kittens)

ACCEPTED
With COMMENTS
In EPA Letter Dated:
JUL 9 2012

Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

2596-164

ACTIVE INGREDIENTS:

Fipronil.....9.70%

OTHER INGREDIENTS90.30%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains (number) tubes, each ____ fl. oz. (____ ml)

EPA Reg. No. 2596-RAU

EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS. CAUTION.

~~Harmful if swallowed.~~ Causes eye irritation. Avoid contact with skin, eyes or clothing. ~~Wash thoroughly with soap and water after handling.~~

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. ~~Individual sensitivities, while rare, may occur after using any pesticide product.~~ Pets may experience some temporary irritation at the site of product application. ~~If signs persist, or become more severe within a few days of application, consult a veterinarian immediately.~~ Certain medications can interact with pesticides. ~~Consult a veterinarian before using on medicated, debilitated or aged animals.~~ Call 1-800-275-1414 for 24-hour assistance.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

~~Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.~~

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: ~~Flush eyes with plenty of water. Call a doctor if irritation persists.~~

IF ON SKIN OR CLOTHING: ~~Wash with plenty of soap and water. Get medical attention if irritation persists.~~

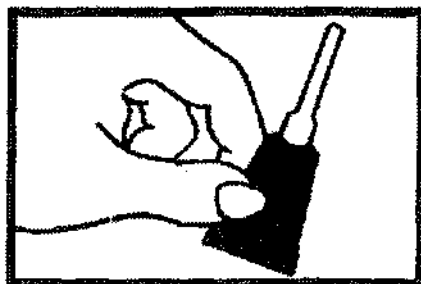
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. **TO PREVENT HARM TO YOU AND YOUR PET READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.**

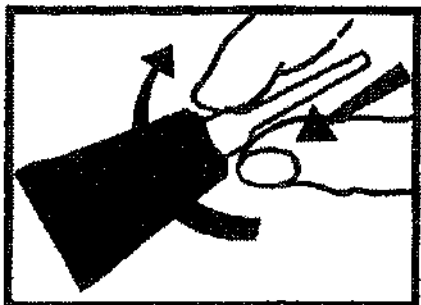
To kill fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks [which may carry Lyme disease], chewing lice and mosquitoes, apply to cats and kittens [8 weeks or older] as follows:

[USE DIRECTIONS HERE]

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)



1 Remove one applicator tube from the package and hold in an upright position pointed away from your face.



2 Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.

3. Position the dispensing tip on the cat's back between the shoulder blades. Use the dispensing tip of the tube to part the cat's hair so that the product will be applied at skin level. Squeeze applicator, applying entire contents in a single spot on the animal's skin. Separate treated cat from other (dogs and cats) (pets) for 24 hours after treatment has been applied.
4. Repeat every month.

PRODUCT NAME contains Fipronil. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

PRODUCT NAME can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

FREQUENCY OF APPLICATION

When used monthly, PRODUCT NAME completely breaks the flea life cycle and controls tick and chewing lice infestations. Research demonstrates that PRODUCT NAME kills adult fleas, flea eggs, and flea larvae for up to six weeks. PRODUCT NAME also prevents development of all flea stages for up to six weeks. PRODUCT NAME kills ticks for a least one month. A once monthly application is recommended where tick control is needed. Although PRODUCT NAME can control fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

With a monthly application of PRODUCT NAME kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days.

PRODUCT NAME remains effective even after bathing, water immersion, or exposure to sunlight. Avoid contact with treated area until dry. Do not reapply PRODUCT NAME for 30 days.

STORAGE AND DISPOSAL

~~Do not contaminate water, food, or feed by storage and disposal.~~

~~STORAGE. Store unused product in original container, out of reach of children and animals.~~

~~PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.~~

~~CONTAINER DISPOSAL. If empty: Do not reuse this container. Place in trash or offer for recycling if available.~~

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am -- 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

Product Name

Active Ingredient:

Fipronil 0.7%

Keep Out of Reach of Children

Caution

Read accompanying label before use

EPA Reg. No. 2596-RAA

EPA Est. No.

OPTIONAL/ALTERNATE LABEL TEXT

Product Name can also be used for the treatment and control of mosquitoes, and flea, tick and chewing lice infestations on breeding, pregnant and lactating queens.

Product Name contains Fipronil. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, chewing lice and mosquitoes.

Stops and prevents infestations

Kills adult Fleas

Kills Fleas which may cause flea allergy dermatitis

Kills all stages of Deer Ticks (which may carry Lyme disease), Brown Dog Ticks, American Dog Ticks, and Lone Star Ticks

Kills mosquitoes

Prevents and controls reinfestations

Rapidly eliminates infestations with chewing lice

Can also be used on breeding, pregnant and lactating queens

Fast-acting

Long-lasting

Waterproof

Convenient to use

[Adult Fleas]

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on cats)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on cats)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations
Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Chewing Lice,
Kills Fleas, Ticks, (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills Fleas, Ticks, (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Kills adult Fleas (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)
Controls Flea and Tick infestations (on cats) (for) (28 days) (30 days) (1 month) (4 weeks)
Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (~~for cats and kittens~~)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)
Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.
Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on cats)
Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on cats)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)

~~Gentle protection for cats (and kittens)~~

~~Quick drying (formula)~~

~~Dries quickly~~

~~Stays on and doesn't rub off~~

~~Spreads with cat's natural skin oils~~

~~Kills fleas for 30 days (1 month) (4 weeks)~~

~~Stops and prevents infestations~~

~~Prevents re-infestation~~

~~Prevents and controls re-infestation(s)~~

~~Rapidly eliminates fleas~~

~~Fast acting~~

~~Long lasting~~

~~Effective and convenient topical treatment~~

First Dose _____
Second Dose _____
Third Dose _____
Xth Dose _____

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

August 10, 2011

MEMORANDUM

Subject: Name of Pesticide Product: HARTZ REFERENCE #130
EPA Reg. No. /File Symbol: 2596-RAL
DP Barcode: DP 388638
Decision No.: 445034
Action Code: R310
PC Codes: 129121 (Fipronil: 9.8%)
105402 (S-Methoprene: 8.8%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
August -10- 2011
Al Backus

To: Bonaventure Akinlosotu/Richard Gebken, RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: THE HARTZ MOUNTAIN CORP.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.80%
105402 (S)-Methoprene	8.80%
<u>Other Ingredient(s):</u>	<u>81.40%</u>
TOTAL	100.00%

ACTION REQUESTED: The Risk Manager requests:

"For your review: An R310."

BACKGROUND:

The material received includes a Form 8570-1 (dated April 28, 2011) that states this product is similar in composition and labelling to EPA Reg. No. 65331-5 (Frontline Plus for Dogs), a CSF dated February 4, 2011, a data matrix dated April 28, 2011 (which indicates the registrant is citing the following MRIDs to satisfy the companion animal safety data requirements: 43863802, 45612702, 45620507 and 45143901), and a proposed label (which indicates dosage rates of 0.023 fl. oz. or 0.67 mL for dogs and puppies weighing up to 22 lbs; 0.045 fl. oz. or 1.34 mL for dogs and puppies weighing 23 to 44 lbs; 0.091 fl. oz. or 2.68 mL for 45 to 88 lbs; and 0.136 fl. oz. or 4.02 mL for 89-132 lbs).

COMMENTS AND RECOMMENDATIONS:

1. After comparing the CSFs for 2596-RAL and EPA Reg. No. 65331-5, TRB concludes that the two formulations are substantially similar in toxicity.
2. From OPPIN, the citation for MRID 43863802 is: *Powell, L.; Paffett, R. (1995) Domestic Animal Safety Study by Topical Administration to Dogs: Fipronil Spot Treatment (RM 1601E): Lab Project Number: MRX 23/950406. Unpublished study prepared by Huntingdon Research Centre, Ltd. 219 p.* From the HED review (TXR 0051187) dated 04/03/96: "the study demonstrated that RM 1001E/62 (9.7% fipronil) has at least a 5X margin of safety in dogs greater than 10 weeks of age."
3. From OPPIN, the citation for MRID 45612702 is: *Nolan-Smith, S. (2001) To Investigate the Safety of a Topical Formulation Containing ML-2,095,988 509T in Dogs Weighing Approximately 2kg (±1.5kg) at One, Three and Five Times the Maximum Label Recommended Dosage: Final Report: Lab Project Number: 1686/12: 1686/12-D2160: PR&D 0045801. Unpublished study prepared by Covance Laboratories. 324 p. {OPPTS 870.7200}.* From the TRB review (TRX 5008387) dated October 21, 2002: "Frontline Plus (active ingredients: 10% w/v fipronil and 9% w/v {S}-methoprene) was topically applied to eight week old dogs weighing less than 11 lbs at 1x, 3x and 5x the prepackaged use (0.67 mL/puppy)... This study (870-7200) is classified **Acceptable** in demonstrating a 5x margin of safety in dogs 8 weeks old or older and weighing less than 11 lbs."
4. From OPPIN, the citation for MRID 45620507 is: *Godin, C.; Alva, R. (2000) ML-2,095,988 509T/Dog/Solution/Topical/Safety/Tolerance/Reproduction. Reactions: Final Report: Lab Project Number: PR&D 0020201: WEL 99885: PR&D 00202. Unpublished study prepared by White Eagle Toxicology Laboratory. 123 p.* From the TRB review (TRX 5008387) dated October 21, 2002: "This study is classified as acceptable. The findings of this study are adequate to support the use of EPA Reg. Nos. 65331-3 and 65331-5 at the specified label use rates (varying according to the weight of dog) at 28-day intervals on breeding, pregnant and lactating bitches."
5. From OPPIN, the citation for MRID 45143901 is: *Nolan-Smith, S. (1999) Fipronil/(S)-Methoprene Topical Solution: Target Species Safety Study in the Dog: Report Amendment: Amendment to Interim Report: Lab Project Number: 1686/2: 1686/2-D1142. Unpublished study prepared by Covance Labs., Ltd. 6 p. {OPPTS 870.7200}*

6. The cited studies in MRIDs 43863802, 45612702, 45620507 and 45143901 are adequate to support the use of this product at the specified application rates in adult dogs, puppies ≥ 8 weeks of age, and on breeding, pregnant and lactating bitches.

7. The proposed label for 2596-RAL includes the claim: "Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks, and chewing lice." In order to have this claim, the registrant has to cite the study in MRID 43577715: *Canovas, M.; Villagellu, J.; Lopez, S.; et al. (1994) Percutaneous Absorption and Hair, Skin, and Fat Distribution of Radioactivity After Spot-On Application of (Carbon 14)-RM1601 in Beagle Dogs: Lab Project Numbers: CD-93/3405F: Q-42.769. Unpublished study prepared by Centro de Investigacion y Desarrollo Aplicado, S.A.L. 68 p.*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

August 5, 2011

MEMORANDUM

Subject: Name of Pesticide Product: HARTZ REFERENCE #130
EPA Reg. No. /File Symbol: 2596-RAL
DP Barcode: DP 388636
Decision No.: 445034
Action Code: R310
PC Codes: 129121 (Fipronil: 9.8%)
105402 (S-Methoprene: 8.8%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
August 5, 2011
B. Hansen

To: Bonaventure Akinlosotu/Richard Gebken, RM 10
Insecticide Branch
Registration Division (7505P)

Registrant: THE HARTZ MOUNTAIN CORP.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
129121 Fipronil	9.80%
105402 (S)-Methoprene	8.80%
<u>Other Ingredient(s):</u>	<u>81.40%</u>
TOTAL	100.00%

ACTION REQUESTED: The Risk Manager requests:

"For your review: An R310."

BACKGROUND:

The material received includes a Form 8570-1 (dated April 28, 2011) that states this product is similar in composition and labelling to EPA Reg. No. 65331-5 (Frontline Plus for Dogs), a CSF dated February 4, 2011, a data matrix dated April 28, 2011 (which indicates the registrant is citing the following MRID studies to satisfy the acute toxicity data requirements: 43951703 [acute oral toxicity]; 44487701 [acute dermal toxicity]; 44433302 [acute inhalation toxicity]; 44942006 [primary eye irritation]; 45612702 [primary dermal irritation]; and 44942008 [dermal sensitization], and a proposed label (which indicates dosage rates of 0.023 fl. oz. or 0.67 mL for dogs and puppies weighing up to 22 lbs; 0.045 fl. oz. or 1.34 mL for dogs and puppies weighing 23 to 44 lbs; 0.091 fl. oz. or 2.68 mL for 45 to 88 lbs; and 0.136 fl. oz. or 4.02 mL for 89-132 lbs).

COMMENTS AND RECOMMENDATIONS:

1. After comparing the CSFs for 2596-RAL and EPA Reg. No. 65331-5, TRB concludes that the two formulations are toxicologically similar.
2. From OPPIN, the citation for MRID 43951703 is: *de Jouffrey, S. (1996) Acute Oral Toxicity in Rats: Frontline Top Spot (RM1601E/62): Lab Project Number: 13450 TAR. Unpublished study prepared by Centre International de Toxicologie. 49 p.* A check of IHAD gives no indication that this study has ever been reviewed. A cursory review of MRID 43951703 (from Documentum) indicates the test material was RM1601E/62, containing 9.92% RM1601 (Fipronil). The rat oral LD₅₀ values with 95% confidence limits were: males: 2515 (1446-5020) mg/kg; females: 3259 (1869-8371) mg/kg. These are consistent with a Toxicity Category III classification by the oral exposure route.
3. From OPPIN, the citation for MRID 44487701 is: *Astruc, B.; Suberville, S.; Bosc, F. et al. (1998) Evaluation of the Presence of M&B 46513 on the Hair After a Topical Application (Spot-on or Spray) of Fipronil to the Dog: Final Report: Lab Project Number: MET419: R002459. Unpublished study prepared by Merial. 28 p.* This is not a dermal LD₅₀ study. According to our records, there is an acceptable rat dermal LD₅₀ study for this formulation (identified as RM1601E/62) in MRID 43577706 (review in TXR 5003209) with assignment to Toxicity Category IV by this exposure route.
4. From OPPIN, the citation for MRID 44433302 is: *Meo, N.; Gonzalez, C.; Mester, T. (1997) Dermal and Inhalation Exposure of Commercial Pet Groomers During Application of Frontline Spray Treatment: Final Report: Lab Project Number: Merial-445-SAFX046: SAFX046: PDA9705. Unpublished study prepared by ABC Labs., California and Animal Appeal Grooming Shop & Case Veterinary Hospital. 1066 p.* This is not an inhalation LC₅₀ study. However, the Agency does not require inhalation LC₅₀ studies on pet spot-on products.
5. From OPPIN, the citation for MRID 44942006 is: *Findlay, J. (1999) Acute Eye Irritation Study of ML-2,095,988 508Q in Rabbits: Final Report: Lab Project Number: 1087SN4: PR&D 00295: PR&D 0029501. Unpublished study prepared by IIT Research Institute (IITRI). 18 p. {OPPTS 870.2400}.* The test material contained 10% fipronil and 12% S-methoprene. According to our records this study has been reviewed (TXR 5001486) and classified as acceptable. This citation can be used to satisfy the primary eye irritation study requirement for 2596-RAL. Although this study indicates a Toxicity Category IV classification by this exposure route, the label of the cited

product (65331-5) includes the precautionary statement: "Causes eye irritation." and there is a first aid statement for eye exposure, so 2596-RAL would be classified in Toxicity Category III by this exposure route.

6. From OPPIN, the citation for MRID 45612702 is: *Nolan-Smith, S. (2001) To Investigate the Safety of a Topical Formulation Containing ML-2,095,988 509T in Dogs Weighing Approximately 2kg (+/-1.5kg) at One, Three and Five Times the Maximum Label Recommended Dosage: Final Report: Lab Project Number: 1686/12: 1686/12-D2160: PR&D 0045801. Unpublished study prepared by Covance Laboratories. 324 p. {OPPTS 870.7200}*. This is not a primary dermal irritation study. According to our records, there is an acceptable primary dermal irritation study which can be used to satisfy this data requirement for 2596-RAL in MRID 44942007. This study was conducted on a formulation containing 10% fipronil and 12% S-methoprene (review in TXR 5001486) with assignment to Toxicity Category IV by this exposure route.
7. From OPPIN, the citation for MRID 44942008 is: *Findlay, J. (1999) Skin Sensitization Study of ML-2,095,988 508Q Using the Modified Buehler Method in Guinea Pigs: Final Report: Lab Project Number: 1087SN5: PR&D 00296: PR&D 0029601. Unpublished study prepared by IIT Research Institute (IITRI). 23 p. {OPPTS 870.2600}*. The test material contained 10% fipronil and 12% S-methoprene. According to our records this study has been reviewed (TXR 5001486) and classified as acceptable; the formulation is not a dermal sensitizer. This study can be used to satisfy the dermal sensitization study requirement for 2596-RAL.
8. TRB concludes that the registrant has given incorrect MRID citations for the dermal LD₅₀, inhalation LC₅₀, and primary dermal irritation studies in the data matrix dated April 28, 2011. These citations should be corrected before TRB makes precautionary and first aid labeling recommendations.
9. This review does not address the companion animal safety study requirements for 2596-RAL.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BARCODE No.: 388835; **FILE SYMBOL No.:** 2596-RAL; **PRODUCT NAME:** Hartz Reference #130;
DECISION No.: 445034; **PC Code(s):** 129121, 105402; **ACTION CODE:** R310; **FOOD Use:** No

DATE OUT: July 27, 2011

SUBJECT: End Use Product Chemistry Review
Product Name: Hartz Reference #130

FROM: Shyam Mathur
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

S. Mathur
7-27-11
mm

TO: Bonaventure Akinlosotu / Richard Gebken, RM 10
Insecticide Branch / RD (7505P)

Company Name: The Hartz Mountain Corporation
Formulation Type: Insecticide

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product "Hartz Reference #130," a liquid flea and tick treatment combination product for dogs and puppies containing Fipronil and (S)-Methoprene. In support of the registration application, the registrant has submitted 830 series group A product chemistry data with MRID Nos. 483790-02 and 483790-03, and 830 series group B data with MRID No. 483790-01. The registrant is using the "cite-all" method of support with Merial (EPA Co. No. 65331). The primary review on the product chemistry data was performed by Summitec Corporation, Knoxville, TN. TRB has been asked to determine the acceptability of the proposed basic CSF and the supporting product chemistry data.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Fipronil (9.80%) and (S)-Methoprene (8.80%)
2. Has the registrant claimed substantial similarity to a registered product?

☐ Yes; ☒ No; ☐ NA; if yes give the registration number of the cited product.

EPA Reg. No: NA

3. All of the source materials of the active ingredient are derived from registered sources- ☒ Yes ☐ No
4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses.

DP BARCODE No.: 388635; FILE SYMBOL No.: 2596-RAL; PRODUCT NAME: Hartz Reference #130;
DECISION No.: 445034; PC Code(s): 129121, 105402; ACTION CODE: R-310; FOOD Use: No

5. Confidential Statement of Formula(s):

☒ Basic - Dated 2/4/2011; Re-submitted – Dated: NA

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid Equivalent: ☐ Yes ☒ NA; acid equivalent =

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite: ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes; ☐ No;

(Combustible: Flashpoint = 40°C, 104°F)

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

DP BARCODE No.: 388635; FILE SYMBOL No.: 2596-RAL; PRODUCT NAME: Hartz Reference #130;
 DECISION No.: 445034; PC Code(s): 129121, 105402; ACTION CODE: R-310; FOOD Use: No

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	483790-02 & CSF
830.1600	Description of materials used to produce the product		X		G	483790-02; MSDSs not provided
830.1650	Description of formulation process		X		A	483790-02
830.1670	Discussion on the formation of impurities		X		A	483790-02
830.1700	Preliminary analysis			X	NA	Not required
830.1750	Certified limits (158.350)	Standard certified limits	X		A	CSF & 483790-02
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	483790-03

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

DP BARCODE No.: 388635; FILE SYMBOL No.: 2596-RAL; PRODUCT NAME: Hartz Reference #130;
 DECISION No.: 445034; PC Code(s): 129121, 105402; ACTION CODE: R-310; FOOD Use: No

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid	A	483790-01 using self-certification (EPA Form No. 8570-36)
830.6315	Flammability	Flashpoint = $40 \pm 1^{\circ}\text{C}$ (104°F)	A	483790-01 using self-certification (EPA Form No. 8570-36)
830.6316	Explodability	Ingredients not potentially explosive	NA	483790-01 using self-certification (EPA Form No. 8570-36)
830.7000	pH	Product is not aqueous	NA	483790-01 using self-certification (EPA Form No. 8570-36).
830.7300	Density (units)	8.33 lb./gal @ 25°C	A	483790-01 using self-certification (EPA Form No. 8570-36)

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress, U = Upgradeable.

DP BARCODE No.: 388635; FILE SYMBOL No.: 2596-RAL; PRODUCT NAME: Hartz Reference #130;
DECISION No.: 445034; PC Code(s): 129121, 105402; ACTION CODE: R-310; FOOD Use: No

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end-use product and has concluded that:

- ✓ 1. The proposed CSF for the basic formulation of Hartz Reference #130 (dated 2/4/2011) is acceptable.
2. The product chemistry data submitted corresponding to guideline 830.1600 (description of materials used to produce the product) are not acceptable. The MSDSs for the starting materials were not provided.
- ✓ 3. The product chemistry data submitted corresponding to guideline 830.1650 (description of the formulation process) are acceptable.
- ✓ 4. The product chemistry data submitted corresponding to guideline 830.1670 (discussion of the formation of impurities) are acceptable.
- ✓ 5. The product chemistry data submitted corresponding to guideline 830.1750 (certified limits) are acceptable.
- ✓ 6. The product chemistry data submitted corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.7100 (viscosity), 830.614 (oxidation/reduction; chemical incompatibility), 830.6315 (flammability), 830.6316 (explosibility), 830.6321 (dielectric breakdown voltage), 830.7000 (pH), and 830.7300 (density) are acceptable. The registrant is using self-certification for the Group B data (EPA Form No. 8570-36).
7. Storage stability (830.6317) data and corrosion characteristics (830.6320) data for the product will be provided when the testing is complete. It is recommended that observations should be made at 0, 3, 6, 9, and 12 month intervals.
8. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the RM team.

DATA EVALUATION RECORD
FIPRONIL AND (S)-METHOPRENE
(HARTZ REFERENCE #130)

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Materials Used to Produce the Product (OPPTS 830.1600)
Description of the Formulation Process (OPPTS 830.1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRIDs 483790-01 through 483790-03

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Sumitree Corporation
9724 Kingston Pike, Suite 602
Knoxville, Tennessee 37922

Task Order No. 3-A-64

Primary Reviewer:
Thomas C. Marshall, Ph.D.

Signature: Thomas C. Marshall, Ph.D.
Date: JUL 25 2011

Secondary Reviewers:
Eric B. Lewis, M.S.

Signature: Eric B. Lewis
Date: JUL 25 2011

Robert Ross, M.S., Program Manager

Signature: Robert H. Ross
Date: JUL 25 2011

Quality Assurance:
Angie Edmonds, B.S.

Signature: Angie Edmonds
Date: JUL 25 2011

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Sumitree Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

Hartz® Reference # 130

Alternate Brand Names

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Treatment for Dogs
Hartz® InControl Max™ Flea (and) (&) Tick Topical Treatment for Dogs

Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Treatment for Dogs

Hartz® Pro Force™ Dual Action Topical Treatment for Dogs
Hartz® FieldForce™ Dual Action Topical Treatment for Dogs
Hartz® First Defense™ Dual Action Topical Treatment for Dogs

Hartz® Pro Force™ for Dogs
Hartz® FieldForce™ for Dogs
Hartz® First Defense™ for Dogs

Hartz® UltraGuard Plus® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® UltraGuard Pro® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® UltraGuard Max™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® InControl Advanced® Flea (and) (&) Tick Topical Solution for Dogs
Hartz® InControl Max™ Flea (and) (&) Tick Topical Solution for Dogs

Revo Advanced™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® Revo Advanced™ Flea (and) (&) Tick Topical Solution for Dogs

Hartz® Pro Force™ Dual Action Topical Solution for Dogs
Hartz® FieldForce™ Dual Action Topical Solution for Dogs
Hartz® First Defense™ Dual Action Topical Solution for Dogs

Hartz® Pro Force™ for Dogs
Hartz® FieldForce™ for Dogs
Hartz® First Defense™ for Dogs

FieldForce™ Dual Action Topical Treatment for Dogs
First Defense™ Dual Action Topical Treatment for Dogs
FieldForce™ for Dogs
First Defense™ for Dogs

FieldForce™ Dual Action Topical Solution for Dogs
First Defense™ Dual Action Topical Solution for Dogs

[Each of the above brands will be packaged in the weight classes designated below:]

Weighing Up to 22 lbs.

Weighing 23 to 44 lbs.

Weighing 45 to 88 lbs.

Weighing 89 - 132 lbs.

ACTIVE INGREDIENTS:

Fipronil.....9.80%

(S)-Methoprene.....8.80%

OTHER INGREDIENTS 81.40%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements.

NET CONTENTS: Contains (number) tubes, each __ fl. oz. (__ ml)

For Dogs and Puppies Weighing:	Net Contents (Each tube)
Up to 22 lbs.	0.023 fl. oz. (0.67 ml.)
23 to 44 lbs.	0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.136 fl. oz. (4.02 ml.)

EPA Reg. No. 2596-RAL

EPA Est. No.

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.

Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

[Cat Warning: A cat prohibition icon will appear on the front panel and back panels, and possibly an additional placement on a side panel.]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on puppies under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few

days of application, consult a veterinarian immediately. If your pet has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE: Do not use or store near heat or open flame.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, you may call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER

THIS PRODUCT IS APPROVED FOR USE ON ALL DOGS, INCLUDING BREEDING, PREGNANT AND LACTATING BITCHES

(The application steps below may optionally be numbered or bulleted to clarify the order, depending on the final physical layout of the label)

[Option 1 capped tube]

Remove one applicator tube from the package and hold in an upright position (pointed away from your face). Pull off cap. Turn the cap around and place on top of tube. Simply press cap down to break the seal of the tube. Remove cap carefully. Position the tip of the tube on the dog's back between the shoulder blades. Use the tip of the tube to part the dog's hair so that the

product will be applied at skin level. (Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the middle of the back.) (Do not bathe your dog 48 hours prior to application.) (Squeeze applicator, applying entire contents in a single spot on the animal's skin) Separate treated dog from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

[Option 2 applicator tube]

Remove one applicator tube from the package and hold in an upright position pointed away from your face. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip. Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. (Begin squeezing out the contents of the tube to form a stripe as you (move) (glide) from the shoulder blades along the dog's back to the middle of the back.) (Do not bathe your dog 48 hours prior to application.) (Squeeze applicator, applying entire contents in a single spot on the animal's skin) Separate treated dog from other (dogs and cats) (pets) for 24 hours after treatment has been applied. Repeat every month.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. *If empty:* Offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

INDIVIDUAL TUBE TEXT

[Product name will be followed by weight of dog for which tube is intended]

[A duplicate weight class designation may be printed on the tube]

Active Ingredients:

Fipronil 9.8%, S-Methoprene 8.8%

Keep Out of Reach of Children

Caution

Read accompanying label before use

[Range of volumes from 0.023 fl. oz. (.67 ml) to 0.136 fl. oz (4.02 ml) depending upon weight of dog]

EPA Reg. No. 2596-RAL

EPA Est. No.

OPTIONAL/ALTERNATE LABEL TEXT

Weighing up to 22lbs lbs.

Weighing 23 - 44 lbs.

Weighing 45 - 88 lbs.

Weighing 89 - 132 lbs.

[Adult Fleas]

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills (Adult) Fleas (for up to 3 months)

Kills fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on dogs)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations

[Flea Eggs]

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of) Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills all biting stages of ticks

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

[Multiple]

Kills Fleas, Ticks, Flea eggs, Chewing Lice, (Flea larvae)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea Eggs, (Flea larvae), (Chewing lice) (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Flea eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents development of all flea stages for up to 3 months.

Kills adult Fleas, Flea Eggs and Larvae (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for dogs and puppies)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

Kills flea eggs and flea larvae to help prevent future re-infestations

Kills all stages of the flea life cycle

Breaks the flea life cycle

Prevents all flea stages (eggs, larvae, pupae) from developing

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs)

Kills Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Prevents flea eggs from developing into biting adults (for) (up to) (30 days) (1 month) (4 weeks)

Gentle protection for dogs (and puppies)

Quick drying (formula)

Dries quickly

Stays on and doesn't rub off

Spreads with dog's natural skin oils

Kills fleas for 30 days (1 month) (4 weeks)

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

(With) patented applicator
(With) patent pending applicator
Waterproof
Easy spot on topical applicator

Do not reapply product for 30 days
Remains effective even after bathing, water immersion, or exposure to sunlight
(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.
Avoid contact with treated area until dry.
Can also be used on breeding, pregnant and lactating bitches
Convenient to use
Contains Fipronil and the insect growth regulator (IGR) (S)-Methoprene. (product name)
effectively targets all stages of fleas. Fipronil collects in the oils of the skin and hair follicles,
and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting
activity against fleas, ticks and chewing lice.

New (Formula) (*claim to be removed after 6 months*)

Contains Fipronil and (S)-Methoprene (, the active ingredients used in Frontline Plus®).
(Brand name) is not manufactured by or distributed by Merial. Frontline Plus® is a registered
trademark of Merial.

Compare to Frontline Plus®

For dogs and puppies 8 weeks of age or older
Specially formulated for dogs and puppies

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose (Xth dose)
First month, second month, third month (Xth month)
X-pack
X-tubes
Value pack
X month supply
X monthly treatment(s)
Fragrance-free
Unscented
Fresh (scent) (fragrance)
Powder (scent) (fragrance)
Pleasant (scent) (fragrance)
Spring Fresh Scent
Convenient (easy to use) applicator
X Pro-cision Flo® Applicator(s)
X Pro-Glide™ Applicator(s)
(Pro-cision Flo® Applicator) (Now) (featuring the angled)

(Pro-Glide™ Applicator) easily gets through dog's fur, for gentle on-skin application
(Pro-cision Flo® Applicator) (Now) (featuring the angled)
(Pro-Glide™ Applicator) quickly gets through dog's fur, for on-skin application
(Pro-cision Flo® Applicator) (Now) (featuring the angled)
(Pro-Glide™ Applicator) easily penetrates dog's fur, for gentle on-skin application
(Pro-cision Flo® Applicator) (Now) (featuring the angled)
(Pro-Glide™ Applicator) quickly penetrates dog's fur, for on-skin application

New Pro-Glide™ Applicator (*To be used only for the first 6 months*)

Pro-Glide™ Applicator gently glides through the dog's fur
Pro-Glide™ Applicator easily gets through dog's fur to minimize (oily) residue
Pro-Glide™ Applicator easily penetrates dog's fur to minimize (oily) residue
Pro-Glide™ Applicator features rounded edges for gentle on-skin application
Pro-Glide™ Applicator glides smoothly through the dog's fur
Pro-Glide™ Applicator features an angled tip to help guide the application
Easy to use Pro-Glide™ Applicator
Direct to your dog's skin
Easy (simple) to use (handle) (apply)
(Featuring the) (with) EZC™ tube
(Featuring the) (with) EZ2C™ tube
(Featuring the) (with) EZView™ tube
(Featuring the) (with) EZView™ tube
(Featuring the) (with) Clearview™ tube
(Featuring the) (with) Clearview™ tube

(Clearview™) (EZC™) (EZ2C™) (EZView™) tube (visually) ensures all product has been dispensed
(Clearview™) (EZC™) (EZ2C™) (EZView™) tubes give you the assurance all the product has been applied

After application, the treated area may appear wet (or) (oily) for up to 24 hours
You may bathe your dog 48 hours after application
To help remind you when you last applied treatment, simply write in the date when each dose is applied:
First Dose _____
Second Dose _____
Third Dose _____
Xth Dose _____

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation

7596 - RAL



Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Workflow Messenger to: Marty Monell, Bonaventure Akinlosotu

08/31/2011 04:03 PM

Sent by: **Marty Monell**

Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Click on this link to access this form:

<https://webforms.epa.gov/webforms/webformsadmin.nsf/formOpen?OpenAgent&UNID=CEAD2D69E9099996852578F0005E0F85&USERDB=webforms/webformsapp.nsf>

Click on this link to access all your forms:

<https://webforms.epa.gov/webforms/webformsapp.nsf>

Recommendation of Division Directors Negotiated Due Dates			
Decision #:	Registration #:	Petition #: N/A	
445034, 445035	2596-RAG, RAU		
442436 & 445037	2596-RAL, RAA		
<input checked="" type="checkbox"/> See page 2 for additional registration entries			
Chemical Name: Fipronil, and Fipronil + S-Methoprene			
Fee Category: R310		PRIA Decision Time Frame: 6 Months	
Submitted by: Bonaventure Akinlosotu		Branch: OCSPP/OPP/RD	Date: 08/18/2011
Company: The Hartz Mountain Corp.			
Original PRIA Due Date: 09/08/2011		Proposed New PRIA Due Date: 03/08/2012	
Previous Negotiated Due Dates:			
Is the "Fix" in house? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		If not, date "Fix" expected: 01/08/2012	
Negotiated Due Date Reason:			
Additional Data Required	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental
	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue <input checked="" type="checkbox"/> Other
Data Deficiencies	<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology
	<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input type="checkbox"/> Labeling <input checked="" type="checkbox"/> Other <input checked="" type="checkbox"/> Not Submitted
Late Risk Assessment	<input type="checkbox"/> Human Health	<input type="checkbox"/> Ecological	
Interim Consideration	<input type="checkbox"/> Agency Initiated	<input checked="" type="checkbox"/> Registrant Initiated	
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health
<input type="checkbox"/> Impurities Review	<input type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input checked="" type="checkbox"/> Other - Comment Field
Summary of Deficiency Type(s): <input checked="" type="checkbox"/> Not Submitted (N) <input checked="" type="checkbox"/> Deficiencies (D)			
Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input checked="" type="checkbox"/>			
CRP data			
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):			
The product reviewer had several discussions with the registrant relative to the CRP requirement (See issues below).			
"75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? Add comments on page 2			
Rationale for Proposed Due Date: Registrant plan to submit CRP data by 01/08/2011			
Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable			
Approve: <input checked="" type="checkbox"/>		Disapprove: <input type="checkbox"/>	
If disapproved, action to be taken:			
OD or DOD Signature: CN=Marty Monell/OU=DC/O=USEPA/C=US		Date: 08/31/2011	

Decision #:	Registration #:	Petition #:
<p>Issue(s) (describe in detail):</p> <p>CRP is required for these products, and the registrant submitted a CRP testing protocol to the Agency for review. The protocol was acceptable with comments, and the Agency notified the registrant on 07/15/2011.</p> <p>After several phone conversations with the registrant to discuss options, the registrant agreed to a 6-month extension. This will allow the registrant to submit required CRP data, and for the Agency to complete the review of all data.</p> <p>The registrant was also notified that all deficiencies must be satisfactorily addressed by 01/08/2012 in order for the Agency to complete the registration process and issue a NOR by the renegotiated date.</p>		
<p>Comment(s):</p>		

Audit Trail for

Recommendation of Division Directors Negotiated Due Dates

PDF Name: PRIAv4a.pdf

Form Number: PRIA

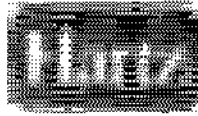
Document Identifier: PRIA-11230130723-BA

SUBMITTED on 08/18/2011 at 02:10:54 PM by CN=Bonaventure Akinlosotu/OU=DC/O=USEPA/C=US

APPROVED on 08/31/2011 at 03:27:38 PM by CN=Marion Johnson/OU=DC/O=USEPA/C=US

APPROVED on 08/31/2011 at 03:39:32 PM by CN=Lois Rossi/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 08/31/2011 at 04:03:34 PM by CN=Marty Monell/OU=DC/O=USEPA/C=US



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094-3688 • 201/271-4800

August 10, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)

RE: HARTZ® Reference No. 128, File Symbol 2596-RAG
HARTZ® Reference No. 129, File Symbol 2596-RAU
HARTZ® Reference No. 130, File Symbol 2596-RAL
HARTZ® Reference No. 131, File Symbol 2596-RAA

PRIA Code R340, Request for Extension of End Date

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094. would like to extend the PRIA conclusion date for these applications in order to provide the Agency sufficient time to review the Child Resistant Packaging data once it is submitted. Hartz is aware of the time requirements for Rosalind Gross to review the data and as a result, it is necessary to request this extension.

After several discussions with Bonaventure Akinlosotu, it was determined that The Hartz Mountain Company will request a 6-month extension, which will change the PRIA conclusion date for these applications from September 8, 2011 to March 8, 2012..

With this extension, Hartz will ensure that the necessary data is submitted in order for EPA to finalize the reviews. We understand that other reviews of our submission packages are well underway and we would like to keep the process moving forward.


If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7202 or <mailto:rosenwasser@hartz.com>.

Sincerely,



Robert Rosenwasser
Director, Regulatory Affairs



Re: PRIA extension request 
Bonaventure Akinlosotu to: RRosenwasser
Cc: Richard Gebken, Marion Johnson

2596-RAU
RAU
RAL
RAA

08/11/2011 10:27 AM

This is to acknowledge receipt of your "Request for Extension of PRIA Due Date", which is being used to initiate the approval process. You will be kept abreast of further actions.

Thanks,

B.A

RRosenwasser

Bonaventure: As discussed, please find attache...

08/10/2011 09:11:40 AM

From: RRosenwasser@hartz.com
To: Bonaventure Akinlosotu/DC/USEPA/US@EPA
Cc: Richard Gebken/DC/USEPA/US@EPA
Date: 08/10/2011 09:11 AM
Subject: PRIA extension request

Bonaventure:

As discussed, please find attached letter. A formal copy is being submitted through the Front End Desk.

Robert

*See copy
of renegoti*

Robert Rosenwasser
Director, Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688
email: rosenwasser@hartz.com
phone: 201-271-4800, ext. 7202[attachment "Hartz PRIA extension.pdf" deleted by Bonaventure Akinlosotu/DC/USEPA/US]



Completed Protocol Review: 2596-RAG, etc.
Bonaventure Akinlosotu to: RRosenwasser
Cc: Richard Gebken, Marion Johnson

07/15/2011 12:22 PM

Mr. Rosenwasser:

Please see attached docs (Cover letter and reviews) relative to the subject action.



[Untitled].pdf



[Untitled].pdf



[Untitled].pdf

Thanks,
B.A.

Bonaventure Akinlosotu, PhD
U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
OPP/RD (Mail Code: 7505P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Physical Address
One Potomac Yard
2777 Crystal Dr.
Arlington, VA 22202

703-605-0653
akinlosotu.bonaventure@epa.gov

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 15, 2011

Robert Rosenwasser, Director
Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Subject: Testing Protocol for Child Resistant Packaging (CRP)
for four (4) Spot-On Fipronil-Containing Products

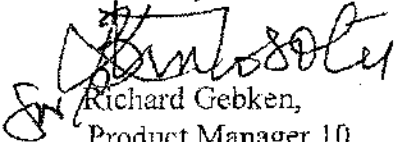
Hartz Reference No. 128: EPA File Symbol 2596-RAG
Hartz Reference No. 129: EPA File Symbol 2596-RAU
Hartz Reference No. 130: EPA File Symbol 2596-RAL
Hartz Reference No. 131: EPA File Symbol 2596-RAA

Submissions dated March 17 and April 28, 2011

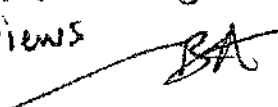
Dear Mr. Rosenwasser:

The above referenced protocol submitted for review by the Agency has been evaluated, and found to be acceptable with the changes provided. Some issues need to be addressed as indicated in the accompanying Agency's "CRP reviews" dated June 2 & 14, 2011. If you have any questions concerning this action please contact Dr. B.A. Akinlosotu at (703) 605-0653.

Sincerely,


Richard Gebken,
Product Manager 10

Insecticide Branch
Registration Division (7505P)

N/A: See 2596-RAG for copies
of reviews


Enclosure Docs: Agency's "CRP Reviews"



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 3, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

THE HARTZ MOUNTAIN CORP.
ATTN: ROBERT ROSENWASSER
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

PRODUCT NAME: HARTZ REFERENCE #130
COMPANY NAME: THE HARTZ MOUNTAIN CORP.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 2596-RAL
EPA RECEIPT DATE: 05/02/11

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 10, at (703) 305-6701.

Sincerely,

J. K. Moore

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division



THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

April 28, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Richard Gebken (PM # 10)**

RE: Agency letter dated March 16, 2011

HARTZ® Reference No. 128, File Symbol 2596-RAG

HARTZ® Reference No. 129, File Symbol 2596-RAU

HARTZ® Reference No. 130, File Symbol 2596-RAL

HARTZ® Reference No. 131, File Symbol 2596-RAA

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting the requested information to satisfy the deficiencies in our registration applications as noted in the Agency letter dated March 16, 2011:

1. New data matrices are submitted for each registration demonstrating the data citations being used for the proposed claims. Public versions are also enclosed. Because Hartz is relying on the selective method of support, new Certifications with Respect to Citation of Data are also submitted.
2. Revised application forms (8570-1) for each are included that demonstrates which of our proposed products is similar in composition and labeling to the related Frontline product.
3. Regarding Child Resistant Packaging (CRP), we are including the Receipt of Protocol Subject to Registration Service Fee (PRIA Code 272) dated March 21, 2011 (MRID 48424401). Any data that demonstrates that fipronil is a neurotoxin above the level of 28.5 mg that may be found in any proposed dose volume (requiring CRP) is information that would be found in the generic database of the technical active and would be captured from the filed Formulator's Exemption for each product. No individual MRID for this information is contained in the supplied Data Matrices.
4. Although not a noted deficiency, Hartz is submitting new CSF's for each product to show the inclusion of [REDACTED].

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7202 or <mailto:rosenwasser@hartz.com>.

Sincerely,

Robert Rosenwasser
Director, Regulatory Affairs

Inert ingredient information may be entitled to confidential treatment



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-RAL	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HARTZ Reference # 130	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 65331-5 Product Name Frontline Plus for Dogs	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New product registration.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
	If "Yes" Unit Packaging wgt. 0.67-4.02 mL	No. per container 1-150	If "Yes" Package wgt.	No. per container	Other (Specify) _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.67-4.02 mL (multiple tubes per		5. Location of Label Directions <input checked="" type="checkbox"/> on outer packaging	
6. Manner in Which Label is Affixed to Product label is printed on packaging <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input checked="" type="checkbox"/> Other inner dosage tubes have required text printed on them	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Robert Rosenwasser	Title Director, Regulatory Affairs	Telephone No. (Include Area Code) 201-971-4800, ext. 7232
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Director, Regulatory Affairs	
4. Typed Name Robert Rosenwasser	5. Date April 28, 2011	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number
 The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094, 201-271-4800

EPA Registration Number/File Symbol
 2596-RAL

Active ingredient(s) and/or representative test compound(s)
 Fipronil, (S)-methoprene

Date
 April 28, 2011

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
 Indoor Residential

Product Name
 Hartz Reference #130

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

April 28, 2011

Typed or Printed Name and Title

Robert Rosenwasser, Director, Regulatory Affairs

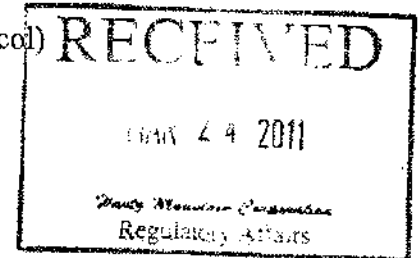


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 21, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-446735
EPA File Symbol or Registration Number: 2596-RAG (CRP testing protocol)
Product Name: HARTZ REFERENCE #128
EPA Receipt Date: 18-Mar-2011
EPA Company Number: 2596
Company Name: THE HARTZ MOUNTAIN CORP.



THE HARTZ MOUNTAIN CORP.
ATTN: ROBERT ROSENWASSER
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Protocol Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your protocol and certification of payment.

If you submitted data with this action, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R272

APPLICANT-INITIATED 2;EXCLUDES DART, PRE-REGISTRATION CONFERENCES,
RAPID RESPONSE REVIEW, DNT PROTOCOL REVIEW, PROTOCOLS NEEDING HSRB
REVIEW;REVIEW OF STUDY PROTOCOL;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

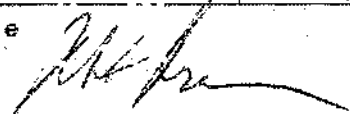
Sincerely, *Teresa Downs*
Front End Processing Staff
Information Technology & Resources Management Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date April 28, 2011			EPA Reg. No. 2596-RAL		Page 1 of 2
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #130		
Ingredient Fipronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition	submitted	Hartz	Own	
830-1600	Beginning materials	submitted	Hartz	Own	
830-1650	Description of formulation process	submitted	Hartz	Own	
830-1670	Formation of impurities	submitted	Hartz	Own	
830-1750	Certified limits	submitted	Hartz	Own	
830-1800	Enforcement analytical method	submitted	Hartz	Own	
830-6302	Color	submitted	Hartz	Own	Self-certification
830-6303	Physical state	submitted	Hartz	Own	Self-certification
830-6304	Odor	submitted	Hartz	Own	Self-certification
830-6314	Oxidation/Reduction	Waiver	Hartz	Own	Self-certification
830-6315	Flammability	submitted	Hartz	Own	Self-certification
830-6316	Explosibility	Waiver	End use product is not potentially explosive.		
830-6317	Storage stability	To be submitted	Hartz	Own	In progress
830-6319	Miscibility	Waiver	End use product is not to be diluted with petroleum solvents.		
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date April 28, 2011

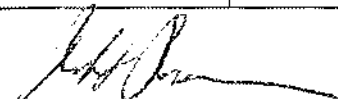


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

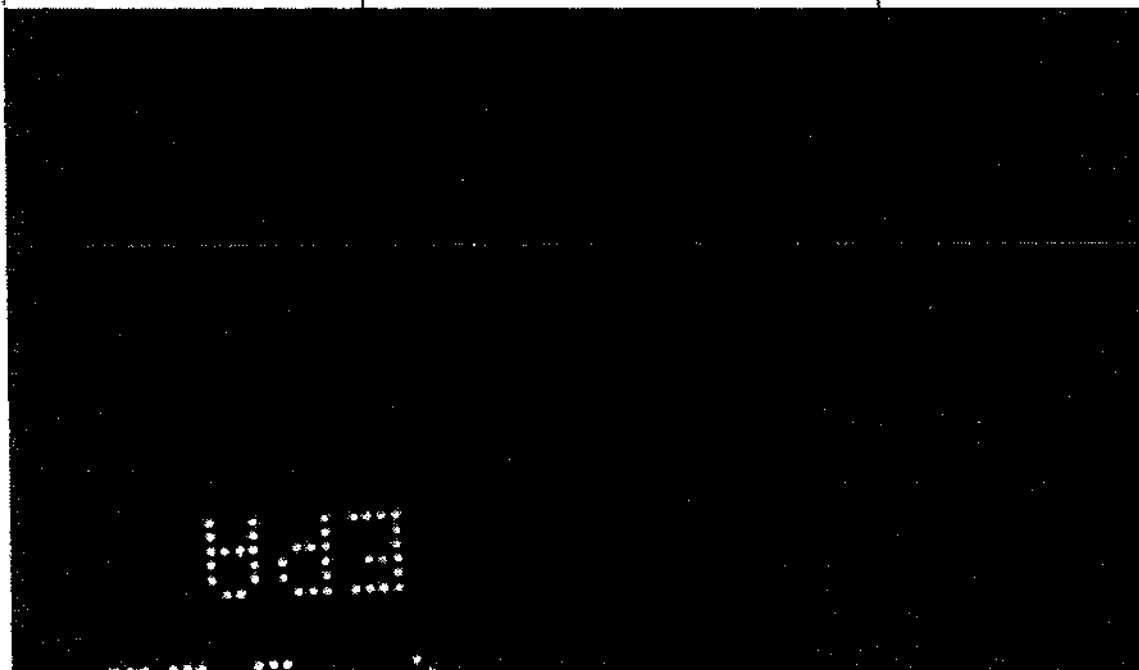

Date April 28, 2011			EPA Reg. No. 2596-RAL		Page 2 of 2
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094			Product Hartz Reference #130		
Ingredient Fipronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-6320	Corrosion characteristics	To be submitted	Hartz	Own	In progress
830-6321	Dielectric breakdown voltage	Waiver	End use product is not to be used around electrical equipment.		
830-7000	pH	Waiver	End use product is not to be dispersed with water.		
830-7100	Viscosity	submitted	Hartz	Own	Self-certification
830-7300	Density	submitted	Hartz	Own	Self-certification
870-1100	Acute oral toxicity	43951703	Merial		
870-1200	Acute dermal toxicity	44487701	Merial		
870-1300	Acute inhalation toxicity	44433302	Merial		
870-2400	Acute eye irritation	44942006	Merial		
870-2500	Acute dermal irritation	45612702	Merial		
870-2500	Skin sensitization	44942008	Merial		
810.3300	Product performance, efficacy	44942105, 44942106, 45612701, 45620501, 45620504, 45620505, 45620506, 445866901, 45866902	Merial		
870.7200	Domestic Animal Safety	43863802, 45612702, 45620507, 45143901	Merial		
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date April 28, 2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date April 28, 2011		EPA Reg. No. 2596-RAL		Page 1 of 2	
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #130			
Ingredient Fipronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
			End use product is not potentially explosive.		
		Hartz	Own	In progress	
		End use product is not to be diluted with petroleum solvents.			
Signature 		Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date April 28, 2011	




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date April 28, 2011		EPA Reg. No. 2596-RAL		Page 2 of 2	
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #130			
Ingredient Fipronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz	Own	In progress
			End use product is not to be used around electrical equipment.		
			End use product is not to be dispersed with water.		
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
			Merial		
			Merial		
			Merial		
			Merial		
			Merial		
			Merial		
			Merial		
			Merial		
			Merial		
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date April 28, 2016



484244-00

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

March 17, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Richard Gebken (PM # 10)
Hartz Reference #128, EPA File Symbol 2596-RAG
Hartz Reference #129, EPA File Symbol 2596-RAU
Hartz Reference #130, EPA File Symbol 2596-RAL ✓
Hartz Reference #131, EPA File Symbol 2596-RAA

**Protocol submission and review for Child Resistant Packaging for
Products containing Fipronil – PRIA action code R272**

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is submitting a protocol for testing of packaging to determine whether packages of end-use products containing the active ingredient, Fipronil, are child resistant.

The testing that will take place after the protocol is approved by EPA will support the registration applications of the 4 products listed above.

The Hartz Mountain Corporation is submitting the following:

48424401

- Hartz Test #2278, Hartz UltraGuard Flea and Tick Topical Treatment, Child-resistant Package Test Protocol, Prepared by National Child Resistant Testing, Inc., Lincoln, NE – 3 copies
- PRIA fee paid by check for \$2,294.00

If you have any questions or need additional information, please feel free to contact me at (201) 271-4800, ext. 7202 or mailto:rosenwasser@hartz.com.

Sincerely,

Robert Rosenwasser
Director, Regulatory Affairs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 16, 2011

Certified Mail: (Article Number 7005-3110-0001-4053-8914)

OPP Decision Numbers: 445034, 445035, 445036 & 445037

Registrant Name: The Hartz Mountain Corp.
(Attn: Robert Rosenwasser, Director, Regulatory Affairs)

Registrant Address: 400 Plaza Drive, Secaucus, NJ 07094

Subject: Data and Labeling Deficiencies

Product Name (EPA File Symbol)

Hartz Ref #s 128 (File Symbol 2596-RAG)

Hartz Ref #s 129 (File Symbol 2596-RAU)

Hartz Ref #s 130 (File Symbol 2596-RAL)

Hartz Ref #s 131 (File Symbol 2596-RAA)

Date of Applications: February 4, 2011

EPA Receipt Date: February 8, 2011

Dear Mr. Rosenwasser:

The Agency has received and begun its in-depth review of each subject applications, and has determined that it is incomplete and that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), also known as the Pesticide Registration Improvement Renewal Act (PRIA 2). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **May 31, 2011** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the applications, or notifying the Agency of the date on which you expect to complete the applications, or withdrawing your applications. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the applications but fail to meet that scheduled date, the Agency will treat the applications as if you had withdrawn it. Withdrawal concludes the Agency's review of your applications. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are as follows:

1. The data matrix for each of the above referenced proposed products is incomplete. You must revise each data matrix accordingly. Instructions for completing the EPA form 8570-35 data matrix correctly can be found within PR Notice 98-5. An electronic copy of this PR Notice can be obtained at the following Agency web site:
http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
 - The data matrix (if using Cite All) must include all companies listed on the data submitters list for each active ingredient. Documentation that offers to pay must be available to the Agency on request. Refer to Section III of the 8570-34 form for specifics.
2. As required on the Application Form (8570-1), no me-too product was listed for each proposed product. Per your request for a PRIA Code R310, you must provide information on the specific product(s) to which each proposed product is similar or identical in composition and labeling.
3. The aforementioned pending applications contain no information on Child Resistant Packaging (CRP) and Companion Animal Safety data.
 - You must provide appropriate information to adequately address CRP and Companion Animal Safety requirements.
 - Child Resistant Packaging is unique for each product, and cannot be cited.
 - The Agency does not accept CRP Self Certification for pending registrations requiring data.

Further review of your applications and your response to the aforementioned deficiencies may reveal additional deficiencies, and you will be so informed.

FIFRA Section 33/PRIA:

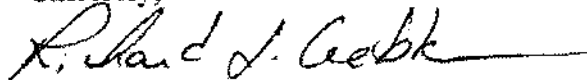
These applications is also subject to a deadline for making a determination on the applications under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA.

The time frame for the Agency to make a determination on each of these applications ends on September 08, 2011; and you have the following three options:

1. **Correct application deficiencies:** All required additional information must adequately address the stated deficiencies, and must be received by the Agency on or before **May 30, 2011**. The Agency will not proceed with the processing of these applications until all the deficiencies are adequately corrected. When all of the required information including acceptable data is received on or before May 31, 2011 by the Agency, you will be notified of the need for additional time and or resources needed to adequately review and process your applications.
2. **Withdraw the applications:** You may notify the Agency before May 31, 2011 that you are withdrawing your applications. As noted above, withdrawal concludes the Agency's review of your applications; however, you may resubmit your applications after the deficiencies have been addressed. Should you choose to resubmit your applications, it would be subject to a new deadline for making a determination on your applications and a new registration service fee. Since a fee was paid with these applications, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond:** If you do not respond or fail to provide the Agency with the above stated information on or before **May 31, 2011**, the Agency will administratively withdraw your applications.

Please respond to this letter by contacting me (Phone: 703-305-6701; e-mail: gebken.richard@epa.gov) or Bonaventure Akinlosotu at (Phone: 703-605-0653; e-mail: akinlostotu.bonaventure@epa.gov) during the hours of 7:00 am to 4:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter must accompany the submission to facilitate processing.

Sincerely,



Richard J. Gebken
Product Manager 10
Insecticide Branch
Registration Division (7505P)



Re: EPA Update for product 2596-RAA, 2596-RAG, 2596-RAU, 2596-RAL

RRosenwasser o Wilkinson Unugboji

02/15/2011 11:32 AM

History: This message has been replied to.

Unugboji:

Please find attached the documents you have requested. This should correct all deficiencies noted.

If you have any questions or need additional information, please give me a call or send an email.

Thanks for your help in this matter.

Robert

Robert Rosenwasser
Director, Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688
email: rosenwasser@hartz.com
phone: 201-271-4800, ext. 7202

Unugboji.Wilkinson@epamail.epa.gov

To: rosenwasser@hartz.com

02/15/2011 10:50 AM

cc

Subject: EPA Update for product 2596-RAA, 2596-RAG, 2596-RAU, 2596-RAL

Hi Mr. Rosenwasser,

Please consider this email as a follow-up to our earlier conversation concerning the deficiencies associated with the application packages being used to support the registration of Hartz Reference #131 (2596-RAA), Hartz Reference #128 (2596-RAG), Hartz Ref #129 (2596-RAU) and Hartz Ref #130 (2596-RAL). Below is the list of deficiencies:

- * The external use data matrix (8570-35) and formulator's exemption statement (8570-27) are missing for all registration packages
- * The method of data support selected on the certification with respect to citation of data (8570-34) for all registration packages is incorrect.

Please email to me the corrections for the deficiencies listed above. If you have any further questions, please feel free to contact me.

Regards,

Unugboji Wilkinson
Data Analyst - MacFadden/EPA Contractor
One Potomac Yard
2777 S. Crystal Drive, S-6921

Arlington, VA 22202
Tel: (703) 347.8518
Fax: (703) 305.5060
EPA mail: unugboji.wilkinson@epa.gov



EPA documents.pdf

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA).
Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis		X				
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method	✓					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor	✓					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)		X				
830.6315	Flammability	✓					
830.6316	Explosibility		X				
830.6317	Storage stability	✓					
830.6319	Miscibility		X				
830.6320	Corrosion Characteristics	✓					
830.6321	Dielectric Breakdown Voltage		X				
830.7000	pH		X				
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	✓					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; Instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)		✓		
870.1200	Acute Dermal (LD50)		/		
870.1300	Acute Inhalation (LC50)		/		
870.2400	Acute Eye Irritation		/		
870.2500	Acute Dermal Irritation		/		
870.2600	Dermal Sensitization		/		

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 14, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

THE HARTZ MOUNTAIN CORP.
ATTN: ROBERT ROSENWASSER
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 08-FEB-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 10, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-445034
EPA File Symbol or Registration Number: 2596-RAL
Product Name: HARTZ REFERENCE #130
EPA Receipt Date: 08-Feb-2011
EPA Company Number: 2596
Company Name: THE HARTZ MOUNTAIN CORP.

THE HARTZ MOUNTAIN CORP.
ATTN: ROBERT ROSENWASSER
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely, *Teresa Owens*
Front End Processing Staff
Information Technology & Resources Management Division



483780-00

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4600
REGULATORY AFFAIRS

February 7, 2011

Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Richard Gebken (PM # 10)**
RE: HARTZ REF #128, EPA Reg. No. 2596-RAG
HARTZ REF #129, EPA Reg. No. 2596-RAU
HARTZ REF #130, EPA Reg. No. 2596-RAL
HARTZ REF #131, EPA Reg. No. 2596-RAA

PRIA CODE = R310

Dear Mr. Gebken:

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688 is filing this application to register 4 new products that are based on the Cite-All Method of Support from Merial.

A complete Transmittal Document is attached which states all the documents that are being submitted in support of this registration.

A check for \$19,228 is also enclosed to cover the application fees for the 4 new products and is submitted under PRIA Code R310.

If you have any questions or need any additional information, please feel free to call me at (201) 271-4800, ext. 7202 or <mailto:rosenwasser@hartz.com>.

Sincerely yours,

Robert Rosenwasser
Director, Regulatory Affairs

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094

2. REGULATORY ACTION IN SUPPORT OF WHICH THESE PACKAGES ARE SUBMITTED

Applications for Registration of 4 new products containing:

Fipronil; Hartz Reference #128, EPA File Symbol 2596-RAG

Fipronil; Hartz Reference #129, EPA File Symbol 2596-RAU

Fipronil and (S)-Methoprene; Hartz Reference #130, EPA File Symbol 2596-RAL

Fipronil and (S)-Methoprene; Hartz Reference #131, EPA File Symbol 2596-RAA

3. TRANSMITTAL DATE February 7, 2011

4. LIST OF SUBMITTED DOCUMENTS

For Reference #128, EPA File Symbol 2596-RAG

VOLUME 1	Product Chemistry Self-Certification	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method Method is also applicable to Hartz Reference #129, EPA File Symbol 2596-RAU	(3 copies)

For Reference #129, EPA File Symbol 2596-RAU

VOLUME 1	Product Chemistry Self-Certification,	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method	(See above)

For Reference #130, EPA File Symbol 2596-RAL

48379001 VOLUME 1	Product Chemistry Self-Certification,	(3 copies)
48379002 VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
48379003 VOLUME 3	Product Chemistry: Enforcement Analytical Method Method is also applicable to Hartz Reference #131, EPA File Symbol 2596-RAA	(3 copies)

For Reference #131, EPA File Symbol 2596-RAA

VOLUME 1	Product Chemistry Self-Certification	(3 copies)
VOLUME 2	Product Chemistry Product Identity and Composition, Analysis, Certification of Ingredients Manufacturing Process Discussion of Impurities Confidential Statement of Formula	(3 copies)
VOLUME 3	Product Chemistry: Enforcement Analytical Method	(See above)

For each application, the following documents are submitted:

1. Completed Application Form (8570-1)
2. Data Matrix
3. Certification with Respect to Citation of Data (8570-34)
4. Data Matrix listing company that is utilized in cite-all method.
5. Completed Confidential Statement of Formulas (One loose copy and one copy in Vol. 2 Product Chemistry)
6. Product labels, 6 copies each.
7. Check in the amount of \$19,228 for 4 applications, PRIA Code R310.

5. COMPANY OFFICIAL Robert Rosenwasser, Director, Regulatory Affairs

6. SIGNATURE

7. PHONE 201-271-4800, ext. 7202



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2596-RAL	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HARTZ Reference # 130	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New product registration.

Section - III

1. Material This Product Will Be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.67-4.02 mL	No. per container 1-150	If "Yes" Package wgt.	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.67-4.02 mL (multiple tubes per		5. Location of Label Directions <input checked="" type="checkbox"/> on outer packaging	
6. Manner in Which Label is Affixed to Product label is printed on packaging		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other inner dosage tubes have required text printed on them	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Robert Rosenwasser		Title Director, Regulatory Affairs		Telephone No. (Include Area Code) 201-271-4800, ext. 7202	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Director, Regulatory Affairs			
4. Typed Name Robert Rosenwasser		5. Date February 4, 2011			

160

Hartz

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

No. 289641

DATE: 07-FEB-11

VENDOR NAME US ENVIRONMENTAL PROTE VENDOR NO. 1992

INVOICE NO	INVOICE DATE	DESCRIPTION	DISCOUNT AMOUNT	NET AMOUNT
REGISTRATI	01-FEB-11	1000023565 P--	0.00	19,228.00
289641A				

PLEASE DETACH AND RETAIN THIS STATEMENT AS YOUR RECORD OF PAYMENT. Thank You!

0.00 19,228.00

THIS CHECK CONTAINS SAFETY FEATURES FRONT AND BACK. DO NOT CASH UNLESS YOU CAN SEE THE WORD "SAFE" WHEN HOLDING AT AN ANGLE.

Hartz

Bank of America

No. 289641



RA-1228
611 GA

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

CHECK DATE 07-FEB-11 CHECK NUMBER 289641 CHECK AMOUNT *****19,228.00

Nineteen Thousand Two Hundred Twenty-Eight Dollars And 00 Cents***

US ENVIRONMENTAL PROTECTION AGENCY
PESTICIDE MAINTENANCE FEES
PO BOX 979031
ST LOUIS, MO 63197-9000

By

By

W. J. H.

289641

Commercial/financial information may be entitled to confidential treatment



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address The Hartz Mountain Corporation 400 Plaza Drive Secacus, NJ 07094	EPA File Symbol/Registration Number 2596-RAL Product Name Hartz Reference 130 Date of Confidential Statement of Formula (EPA Form 8570-4) 02/04/2011	
As an authorized representative of the applicant for registration of the product identified above, I certify that:		
(1) This product contains the following active ingredient(s): Fipronil (S)-Methoprene		
(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).		
(3) Indicate by checking (A) or (B) below which paragraph applies:		
<input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).		
OR		
<input type="checkbox"/> (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.		
(4) The following active ingredients in this product qualify for the formulator's exemption.		
Source		
Active Ingredient	Product Name	Registration Number
5-Amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-4	[REDACTED]	[REDACTED]
[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile	[REDACTED]	[REDACTED]
CAS# 122068-37-3	[REDACTED]	[REDACTED]
(S)-Methoprene CAS # 65733-16-6	[REDACTED]	[REDACTED]
Signature	Name and Title	Date
	R. Rosenwasser, Dir, Reg. Affairs	02/15/2011

EPA Form 8570-27 (Rev. 06-2004)

 Copy 1 - EPA
 Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094, 201-271-4800	EPA Registration Number/File Symbol 2596-RAL
Active Ingredient(s) and/or representative test compound(s) Fipronil, (S)-methoprene	Date February 15, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor Residential	Product Name Hartz Reference #130

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (for cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (f) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (f) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

2/15/2011

Typed or Printed Name and Title

Robert Rosenwasser, Director, Regulatory Affairs



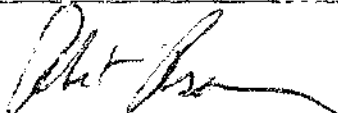
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date February 4, 2011	EPA Reg. No. 2596-RAL	Page 1 of 2
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #130

Ingredient Fipronil, (S)-methoprene

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product identification and composition	submitted	Hartz	Own	
830-1600	Beginning materials	submitted	Hartz	Own	
830-1650	Description of formulation process	submitted	Hartz	Own	
830-1670	Formation of impurities	submitted	Hartz	Own	
830-1750	Certified limits	submitted	Hartz	Own	
830-1800	Enforcement analytical method	submitted	Hartz	Own	
830-6302	Color	submitted	Hartz	Own	Self-certification
830-6303	Physical state	submitted	Hartz	Own	Self-certification
830-6304	Odor	submitted	Hartz	Own	Self-certification
830-6314	Oxidation/Reduction	Waiver	Hartz	Own	Self-certification
830-6315	Flammability	submitted	Hartz	Own	Self-certification
830-6316	Exp'dability	Waiver	End use product is not potentially explosive.		
830-6317	Storage stability	To be submitted	Hartz	Own	In progress
830-6318	Miscibility	Waiver	End use product is not to be diluted with petroleum solvents.		
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date February 4, 2011



Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Date	February 4, 2011	EPA Reg. No. 2596-RAL	Page 2 of 2
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #130	

[illegible]

Date
February 4, 2011



Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Date	February 4, 2011	EPA Reg. No. 2596-RAL	Page 1 of 1
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #130	

[illegible]



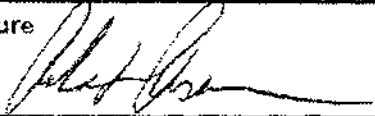
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director: OPPE Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX


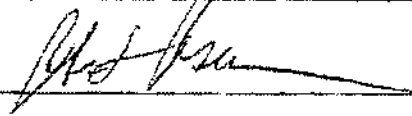
Date February 15, 2011		EPA Reg. No. 2596-RAL		Page 1 of 2	
Applicant's/Registrant's Name & Address: Hartz Mountain Corporation, 400 Plaza Dr., Secaucus, NJ 07094		Product Hartz Reference #130			
Ingredient Fipronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
			End use product is not potentially explosive.		
Hartz			Own	In progress	
End use product is not to be diluted with petroleum solvents.					
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date February 15, 2011



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Ingredient Fipronil, (S)-methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Hartz	Own	In progress
			End use product is not to be used around electrical equipment.		
			End use product is not to be dispersed with water.		
			Hartz	Own	Self-certification
			Hartz	Own	Self-certification
Signature 			Name and Title Robert Rosenwasser Director, Regulatory Affairs		Date February 15, 2011

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAi). Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or (NO) (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAi	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis		✓				
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method	✓					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAi	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor	✓					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical Incompatibility)		✓				
830.6315	Flammability	✓					
830.6316	Explosibility		✓				
830.6317	Storage stability		✓				
830.6319	Miscibility		✓				
830.6320	Corrosion Characteristics		✓				
830.6321	Dielectric Breakdown Voltage		✓				
830.7000	pH		✓				
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	✓					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)		✓		
870.1200	Acute Dermal (LD50)		✓		
870.1300	Acute Inhalation (LC50)		/		
870.2400	Acute Eye Irritation		/		
870.2500	Acute Dermal Irritation		/		
870.2600	Dermal Sensitization		/		

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					

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Confidential Statements of Formula may be entitled to confidential treatment